EXHIBIT A

EXHIBIT A – JOINT STATEMENT OF UNCONTESTED FACTS

The following facts are not disputed or have been agreed to or stipulated to by the parties:

Parties

1. Abbott Laboratories is a corporation organized and existing under the laws of the State of Illinois, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

2. Abbott Respiratory LLC ("Abbott Respiratory") is a limited liability corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064.

3. Watson is a corporation organized under the laws of the State of Florida having a place of business at 4955 Orange Drive, Davie, Florida 33314.

SIMCOR® NDA

4. Abbott Laboratories is listed by the FDA as the holder of New Drug Application ("NDA") No. 22-078. Abbott manufactures and sells SIMCOR®, an extended-release form of niacin/simvastatin. SIMCOR® was approved by the FDA on February 15, 2008. Abbott currently sells 500 mg/20 mg, 500 mg/40 mg, 750 mg/20 mg, 1000 mg/20 mg, and 1000 mg/40 mg dosage strengths of SIMCOR®.

Watson's ANDA

5. On December 2, 2009, Watson filed ANDA No. 20-0601 seeking FDA approval to market a 1000 mg/20 mg extended-release niacin/simvastatin product ("the 1000 mg/20 mg Watson Product"), which is a generic version of Abbott's 1000 mg/20 mg SIMCOR® product.

6. On February 9, 2011, Watson filed an amendment to ANDA No. 20-0601 seeking FDA approval to market a 500 mg/40 mg extended-release niacin/simvastatin product ("the 500

mg/40 mg Watson Product"), which is a generic version of Abbott's 500 mg/40 mg SIMCOR® product.

7. The 500 mg/40 mg Watson Product satisfies the FDA's criteria for establishing bioequivalence of its product to the reference listed drug, the 500 mg/40 mg SIMCOR® product marketed by Abbott.

8. The 1000 mg/20 mg Watson Product satisfies the FDA's criteria for establishing bioequivalence of its product to the reference listed drug, 1000 mg/20 mg SIMCOR® product marketed by Abbott.

Procedural History

9. The Watson ANDA contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), asserting that the patents-in-suit are invalid and/or will not be infringed by the manufacture, use, offer for sale, or sale of the Watson Products.

10. On March 25, 2010, pursuant to 21 U.S.C. § 355(j)(2)(B)(iii)-(iv), Watson provided Abbott notice of its ANDA and certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) concerning the 1000 mg/20 mg Watson Product for each of the patents-in-suit.

11. On May 4, 2010, Abbott brought a separate action (C.A. No. 10-373) against Watson under 35 U.S.C. § 271(e) asserting infringement of the patents-in-suit by the 1000 mg/20 mg Watson Product.

12. On July 20, 2010, upon the request of the parties, the Court consolidated C.A. No. 10-373 with the lead action (C.A. No. 10-57).

13. On February 9, 2011, pursuant to 21 U.S.C. § 355(j)(2)(B)(iii)-(iv), Watson provided Abbott notice of its ANDA amendment and certifications under 21 U.S.C.

§ 355(j)(2)(A)(vii)(IV) concerning the 500 mg/40 mg Watson Product for each of the patents-in-suit.

14. On March 25, 2011, Abbott brought a separate action (C.A. No. 11-251) against Watson under 35 U.S.C. § 271(e) asserting infringement of the patents-in-suit by the 500 mg/40 mg Watson Product.

15. On May 24, 2011, upon the request of the parties, the Court consolidated C.A. No. 11-251 with the lead action (C.A. No. 10-57).

The '428 Patent

16. The '428 patent is entitled "Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Therefor." The '428 patent issued on June 27, 2000 and expires on May 27, 2017. David J. Bova is the named inventor of the '428 patent.

17. The '428 patent was filed on January 14, 1995 and claims priority as a continuation-in-part to Application No. 08/368,392, filed September 20, 1993.

18. Abbott owns the '428 patent and has the rights granted under 35 U.S.C. § 154(a) to the extent not conveyed to others, and to the extent the claims of the patent are found not invalid.

19. The '428 patent is listed for SIMCOR® in the FDA's listing of Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

20. Abbott is asserting infringement of claims 1, 3, 5, 6, and 8 of the '428 patent by the 1000 mg/20 mg Watson Product. Watson alleges that these claims of the '428 patent are invalid and/or not infringed.

The ’930 Patent

21. The ’930 patent is entitled “Methods and Sustained Release Nicotinic Acid Compositions for Treating Hyperlipidemia at Night.” The ’930 patent issued on October 10, 2000 and expires on September 20, 2013. David J. Bova is the named inventor of the ’930 patent.

22. The ’930 patent was filed on March 6, 1997 and claims priority as a continuation-in-part to Application No. 08/368,392, filed September 20, 1993. The ’930 patent issued from Application No. 08/814,974, which is a continuation-in-part of the application that ultimately issued as the ’428 patent.

23. Abbott owns the ’930 patent and has the rights granted under 35 U.S.C. § 154(a) to the extent not conveyed to others, and to the extent the claims of the patent are found not invalid.

24. The ’930 patent is listed for SIMCOR® in the FDA’s Orange Book.

25. Abbott is asserting infringement of claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 by the 1000 mg/20 mg Watson Product. Watson alleges these claims of the’930 patent are invalid and/or not infringed.

The ’848 patent

26. The ’848 patent bears on its face the title “Hydrophobic Component Free Sustained Release Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Therefor.” On June 15, 2004, before the ’848 patent issued, an amendment after allowance was filed to correct the title of the ’848 patent to read: “Nicotinic Acid Compositions for Treating Hyperlipidemia and Related Methods Therefor,” which the Patent and Trademark

Office entered on December 7, 2004. The ’848 patent issued on March 14, 2006 and expires on September 20, 2013. David J. Bova is the named inventor of the ’848 patent.

27. The ’848 patent was filed on December 22, 1999 and claims priority as a continuation-in-part to Application No. 08/368,392, filed September 20, 1993. The application resulting in the ’848 patent was a continuation of Application No. 08/814,974, which ultimately issued as the ’930 patent.

28. Abbott owns the ’848 patent and has the rights granted under 35 U.S.C. § 154(a) to the extent not conveyed to others, and to the extent the claims of the patent are found not invalid.

29. The ’848 patent is listed for SIMCOR® in the FDA’s Orange Book.

30. Abbott is asserting infringement of claims 1, 3, 5, 6, and 8 of the ’848 patent by the 1000 mg/20 mg Watson product. Watson alleges that these claims of the ’848 patent are invalid and/or not infringed.

The ’715 Patent

31. The ’715 patent is entitled “Intermediate Release Nicotinic Acid Compositions for Treating Hyperlipidemia Having Unique Urinary Metabolite Profiles.” The ’715 patent issued on June 18, 2002 and expires on September 20, 2013. David J. Bova and Eugenio A. Cefali are the named inventors of the ’715 patent.

32. The ’715 patent issued from Application No. 08/962,423 (“the ’423 application”), filed October 31, 1997. The ’423 application was a continuation-in-part of Application No. 08/814,974, which subsequently issued as the ’930 patent.

33. Abbott owns the ’715 patent and has the rights granted under 35 U.S.C. § 154(a) to the extent not conveyed to others, and to the extent the claims of the patent are found not invalid.

34. The ’715 patent is listed for SIMCOR® in the FDA’s Orange Book.

35. Abbott is asserting infringement of claims 1, 3, and 5 of the ’715 patent by the 500 mg/40 mg Watson Product. Watson alleges that these claims of the ’715 patent are invalid and/or not infringed.

36. Abbott is asserting infringement of claims 9 and 11 of the ’715 patent by the 1000 mg/20 mg Watson Product. Watson alleges that these claims of the ’715 patent are invalid and/or not infringed.

The ’229 Patent

37. The ’229 patent is entitled “Intermediate Release Nicotinic Acid Compositions for Treating Hyperlipidemia.” The ’229 patent issued on November 16, 2004 and expires on September 20, 2013. David J. Bova and Eugenio A. Cefali are the named inventors of the ’229 patent.

38. The ’229 patent issued from Application No. 08/962,027 (“the ’027 application”), filed October 31, 1997. The ’027 application was a continuation-in-part of Application No. 08/814,974, which subsequently issued as the ’930 patent.

39. Abbott owns the ’229 patent and has the rights granted under 35 U.S.C. § 154(a) to the extent not conveyed to others, and to the extent the claims of the patent are found not invalid.

40. The ’229 patent is listed for SIMCOR® in the FDA’s Orange Book.

41. Abbott is asserting infringement of claims 9 and 11 of the ’229 patent by the 500 mg/40 mg Watson Product. Watson alleges that these claims are invalid and/or not infringed.

42. Abbott is asserting infringement of claims 25 and 27 of the ’229 patent by the 1000 mg/20 mg Watson Product. Watson alleges that these claims of the ’229 patent are invalid and/or not infringed.

The ’967 Patent

43. The ’967 patent is entitled “Methods for Reducing Flushing in Individuals Being Treated with Nicotinic Acid for Hyperlipidemia.” The ’967 patent issued on January 13, 2004 and expires on September 20, 2013. David J. Bova and Eugenio A. Cefali are the inventors of the ’967 patent.

44. The ’967 patent issued from Application No. 08/962,422 (“the ’422 application”), filed October 31, 1997. The ’422 application was a continuation-in-part of Application No. 08/814,974, which subsequently issued as the ’930 patent.

45. Abbott owns the ’967 patent and has the rights granted under 35 U.S.C. § 154(a) to the extent not conveyed to others, and to the extent the claims of the patent are found not invalid.

46. The ’967 patent is listed for SIMCOR® in the FDA’s Orange Book.

47. Abbott is asserting infringement of claims 16, 18, 25, and 26 of the ’967 patent by the 1000 mg/20 mg Watson Products. Watson alleges that these claims of the ’967 patent are invalid and/or not infringed.

The ’691 Patent

48. The ’691 patent is entitled “Intermediate Release Nicotinic Acid Compositions for Treating Hyperlipidemia Having Unique Biopharmaceutical Characteristics.” The ’691 patent

issued June 8, 2004 and expires on September 20, 2013. Eugenio A. Cefali is the inventor of the '691 patent.

49. The '691 patent issued from Application No. 08/962,424 ("the '424 application"), filed October 31, 1997. The '424 application was a continuation-in-part of Application No. 08/814,974, which subsequently issued as the '930 patent.

50. Abbott owns the '691 patent and has the rights granted under 35 U.S.C. § 154(a) to the extent not conveyed to others, and to the extent the claims of the patent are found not invalid.

51. The '691 patent is listed for SIMCOR® in the FDA's Orange Book.

52. Abbott is asserting infringement of claims 1 and 3 of the '691 patent by the 500 mg/40 mg Watson Product. Watson alleges that claims 1 and 3 of the '691 patent are invalid and/or not infringed.

53. Abbott is asserting infringement of claims 13 and 15 of the '691 patent by the 1000 mg/20 mg Watson Product. Watson alleges that these claims of the '691 patent are invalid and/or not infringed.

The '035 Patent

54. The '035 patent is entitled "Methods of Pretreating Hyperlipidemic Individuals with a Flush Inhibiting Agent Prior to the Start of Single Daily Dose Nicotinic Acid Therapy to Reduce Flushing Provoked by Nicotinic Acid." The '035 patent issued October 22, 2002 and expires on March 15, 2018. Eugenio A. Cefali is the inventor of the '035 patent.

55. The '035 patent issued from Application No. 08/903,755, filed July 31, 1997.

56. Abbott owns the '035 patent and has the rights granted under 35 U.S.C. § 154(a) to the extent not conveyed to others, and to the extent the claims of the patent are found not invalid.

57. The '035 patent is listed for SIMCOR® in the FDA's Orange Book.

58. Abbott is alleging infringement of claims 2-5, 11-13, and 21-30 of the '035 patent by the 1000 mg/20 mg Watson Product. Watson alleges that these claims of the '035 patent are invalid and/or not infringed.

500 mg/40 mg Watson Product

59. The 500 mg/40 mg Watson Product is suitable for oral administration.

60. The 500 mg/40 mg Watson Product is a tablet.

61. Watson's proposed labeling, when approved by the FDA, recommends that the 500 mg/40 mg Watson Product may be taken as directed by a physician, including once daily.

62. The proposed labeling for the 500 mg/40 mg Watson Product instructs that it should be given at bedtime.

63. The 500 mg/40 mg Watson Product contains nicotinic acid.

64. The 500 mg/40 mg Watson Product contains one or more excipients to provide for the sustained release of nicotinic acid.

65. The 500 mg/40 mg Watson Product can be characterized as including, among other things, an intermediate release nicotinic acid formulation.

66. The 500 mg/40 mg Watson Product satisfies the FDA criteria for bioequivalence to Abbott's 500 mg/40 mg SIMCOR® product.

67. The proposed labeling for the 500 mg/40 mg Watson Product recommends against doses greater than 2000 mg/40 mg of nicotinic acid/simvastatin daily.

68. Abbott does not assert that the 500 mg/40 mg Watson Product infringes the ’428, ’930, ’848, ’967 or ’035 patents.

1000 mg/20 mg Watson Product

69. The 1000 mg/20 mg Watson Product is suitable for oral administration.

70. The 1000 mg/20 mg Watson Product is a tablet.

71. Watson’s proposed labeling, when approved by the FDA, recommends that the 1000 mg/20 mg Watson Product may be taken as directed by a physician, including once daily.

72. The proposed labeling for the 1000 mg/20 mg Watson Product instructs that it should be given at bedtime.

73. The 1000 mg/20 mg Watson Product contains nicotinic acid.

74. The 1000 mg/20 mg Watson Product contains one or more excipients to provide for the sustained release of nicotinic acid.

75. Like NIASPAN®, ADVICOR®, and SIMCOR®, the 1000 mg/20 mg Watson Product can be characterized as including a sustained release nicotinic acid formulation, an intermediate nicotinic acid formulation, and an extended release nicotinic acid formulation.

76. The HMG-CoA reductase inhibitor in the 1000 mg/20 mg Watson Product is in an immediate release form.

77. The 1000 mg/20 mg Watson Product includes an inner core containing the extended release nicotinic acid that is coated with a layer containing the immediate release HMG-CoA reductase inhibitor.

78. The 1000 mg/20 mg Watson Product satisfies the FDA criteria for bioequivalence to Abbott’s 1000 mg/20 mg SIMCOR® product.

79. The proposed labeling for the 1000 mg/20 mg Watson Product recommends against doses greater than 2000 mg/40 mg of nicotinic acid/simvastatin daily.

EXHIBIT B

EXHIBIT B – ABBOTT'S BRIEF STATEMENT OF WHAT IT INTENDS TO PROVE IN SUPPORT OF ITS CLAIMS

Abbott hereby submits its brief statement of intended proof to be litigated. The following statements are not exhaustive, and Abbott reserves the right to prove any matters identified in its pleadings, interrogatory responses, and/or expert reports. Abbott also intends to offer evidence as to the issues of fact and issues of law identified in this pretrial order. Abbott further intends to offer evidence to rebut evidence that Watson offers. Abbott reserves the right to amend and supplement these statements in response to Watson's pretrial activities or any subsequent produced discovery. Abbott incorporates by reference its expert reports in support of any proof to be presented by expert testimony.

INFRINGEMENT

Abbott intends to prove at trial that the commercial manufacture, use, offering for sale, or sale of Watson's 500 mg/40 mg Product will infringe claims 1, 3, and 5 of the '715 patent; claims 9 and 11 of the '229 patent; and claims 1 and 3 of the '691 patent.

Abbott further intends to prove at trial that the commercial manufacture, use, offering for sale, or sale of Watson's 1000 mg/20 mg Product will infringe, directly or indirectly through inducement, claims 1, 3, 5, 6, and 8 of the '428 patent; claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the '930 patent; claims 1, 3, 5, 6, and 8 of the '848 patent; claims 9 and 11 of the '715 patent; claims 25 and 27 of the '229 patent; claims 13 and 15 of the '691 patent; claims 16, 18, 25, and 26 of the '967 patent; and claims 2-5, 11-13, and 21-30 of the '035 patent.

VALIDITY

Watson bears the burden of proof on invalidity. To the extent Watson is able to establish a *prima facie* case of invalidity, Abbott intends to present evidence rebutting the evidence Watson presents in support of its invalidity defenses and counterclaims. Abbott reserves its right

to present appropriate rebuttal evidence in response to the invalidity arguments Watson chooses to present at trial.

(a) Anticipation

With respect to Watson's allegations that claims 2-5 and 11-13 of the '035 patent and the asserted claims of the '428, '930, '848, '715, '229, '691, and '967 patents are invalid as anticipated by the prior art, Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence that any individual prior art reference on which they rely discloses, either explicitly or inherently, all of the limitations of the asserted claim that it is alleged to anticipate.

(b) Obviousness

With respect to Watson's allegations that the asserted claims of the '428, '930, '848, '715, '229, '691, '967, and '035 patents are invalid as obvious in light of the prior art (either alone or in combination), Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence that the inventions claimed in the asserted claims would have been obvious to a person of ordinary skill in the art at the time the inventions were made in view of the asserted prior art.

To the extent Watson is able to establish a *prima facie* case of obviousness, Abbott will present evidence of unexpected results and secondary considerations of non-obviousness, including long-felt need, skepticism, third-party praise, failure of others, copying, licensing, and commercial success.

(c) Written Description

With respect to Watson's allegation that claim 3 of the '428 patent is invalid for failure to provide sufficient written description, Abbott will show that Watson has failed to satisfy its

burden of proving by clear and convincing evidence that the patent's specification fails to describe the invention in sufficient detail so that a person of ordinary skill in the art can clearly conclude that the inventor invented what is claimed.

With respect to Watson's allegation that claim 3 of the '848 patent is invalid for failure to provide sufficient written description, Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence that the patent's specification fails to describe the invention in sufficient detail so that a person of ordinary skill in the art can clearly conclude that the inventor invented what is claimed.

With respect to Watson's allegation that claims 2-5, 11-13, 21, and 26-30 of the '035 patent are invalid for failure to provide sufficient written description, Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence that the patent's specification fails to describe the invention in sufficient detail so that a person of ordinary skill in the art can clearly conclude that the inventor invented what is claimed.

With respect to Watson's allegations that the asserted claims of the '930, '715, '229, '691, and '967 patents are invalid for failure to provide sufficient written description, Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence that the patent's specification fails to describe the inventions in sufficient detail so that a person of ordinary skill in the art can clearly conclude that the inventors invented what is claimed.

(d) Enablement

With respect to Watson's allegation that the specification of the '428 patent does not enable the full scope of claim 3, Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence that a person of ordinary skill in the art would be unable to make or use the claimed invention without undue experimentation.

With respect to Watson's allegation that the specification of the '848 patent does not enable the full scope of claim 3, Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence that a person of ordinary skill in the art would be unable to make or use the claimed invention without undue experimentation.

With respect to Watson's allegation that the specification of the '035 patent does not enable to the full scope of claims 2-5, 11-13, 21, and 26-30, Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence that a person of ordinary skill in the art would be unable to make or use the claimed invention without undue experimentation.

With respect to Watson's allegations that the specifications of the '930, '715, '229, '691, and '967 patents do not enable the full scope of the asserted claims, Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence that a person of ordinary skill in the art would be unable to make or use the claimed inventions without undue experimentation.

(e) Indefiniteness

With respect to Watson's allegations that a person having ordinary skill in the art would not understand the scope of claim 3 of the '428 patents, Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence that a person of ordinary skill in the art could not discern the boundaries of the claims based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant area.

With respect to Watson's allegations that a person having ordinary skill in the art would not understand the scope of claims 2-5, 11-13, 21, and 26-30 of the '035 patents, Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence

that a person of ordinary skill in the art could not discern the boundaries of the claims based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant area.

With respect to Watson's allegations that a person having ordinary skill in the art would not understand the scope of the asserted claims of the '930, '848, '715, '229, '691, '967 patents, Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence that a person of ordinary skill in the art could not discern the boundaries of the claims based on the claim language, the specifications, and the prosecution histories, as well as her knowledge of the relevant area.

(f) Best Mode

With respect to Watson's allegation that the inventor of the '428 patent failed to disclose the best mode of the invention, Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence that, at the time the patent application was filed, the inventor possessed a best mode of practicing the claimed invention, and, if so, that he concealed the preferred mode from the public.

(g) Obviousness-Type Double Patenting

With respect to Watson's allegation that the asserted claims of the '035 patent are invalid under the doctrine of obviousness-type double patenting in view of the '930, '848, '715, '229, '691, and '967 patents, Abbott will show that Watson has failed to satisfy its burden of proving by clear and convincing evidence that a person of ordinary skill in the art at the time the invention was made would have considered the invention claimed in the '035 patent an obvious variation of the inventions claimed in the '930, '848, '715, '229, '691, and '967 patents.

EXHIBIT C

EXHIBIT C – ABBOTT'S STATEMENT OF CONTESTED FACTS

The operative claims in this matter are set forth in the complaints filed by Plaintiffs Abbott Laboratories and Abbott Respiratory LLC (collectively, "Abbott"), which allege infringement of United States Patent Nos. 6,080,428 ("the '428 patent"), 6,129,930 ("the '930 patent"), 7,011,848 ("the '848 patent"), 6,818,229 ("the '229 patent"), 6,406,715 ("the '715 patent"), 6,676,967 ("the '967 patent"), 6,746,691 ("the '691 patent"), and 6,469,035 ("the '035 patent") (collectively, "the patents-in-suit") by Watson Laboratories, Inc. – Florida ("Watson"). In response to the complaints, Watson has asserted various defenses, including non-infringement and invalidity of the patents-in-suit, and has sought a declaratory judgment that the patents-in-suit are not infringed and invalid.

Abbott's identification of the issues of fact that remain to be litigated is based on its current understanding of the arguments Watson is likely to make in attempting to prove non-infringement and invalidity, based upon the pleadings and discovery in the action to date. To the extent that Watson intends or attempts to introduce different or additional facts to meet its burden of proof, Abbott reserves its rights to contest those facts, and to present any and all rebuttal evidence in response to those facts.

In addition, to the extent that Abbott's Statement of the Issues of Law that Remain to Be Litigated contain issues of fact, those issues are incorporated herein by reference, and to the extent the Court determines that any issue identified in this list as an issue of fact is more properly construed as an issue of law, Abbott incorporates such issue by reference into its Statement of the Issues of Law that Remain to Be Litigated.

Based on Abbott's current understanding of Watson's defenses, Abbott believes the following issues of fact remain to be litigated:

1. Whether Watson's proposed generic 500 mg/40 mg extended-release niacin/simvastatin product ("the 500 mg/40 mg Watson Product") meets the limitations of claims 1, 3, and 5 of the '715 patent;

2. Whether the 500 mg/40 mg Watson Product meets the limitations of claims 9 and 11 of the '229 patent;

3. Whether the 5000 mg/40 mg Watson Product meets the limitations of claims 1 and 3 of the '691 patent;

4. Whether the use of Watson's proposed generic 1000 mg/20 mg extended-release niacin/simvastatin product ("the 1000 mg/20 mg Watson Product") in accordance with Watson's proposed labeling meets the limitations of claims 1, 3, 5, 6, and 8 of the '428 patent;

5. Whether the 1000 mg/20 mg Watson Product, or its use in accordance with Watson's proposed labeling, meets the limitations of claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the '930 patent;

6. Whether the use of the 1000 mg/20 mg Watson Product in accordance with Watson's proposed labeling meets the limitations of claims 1, 3, 5, 6, and 8 of the '848 patent;

7. Whether the 1000 mg/20 mg Watson Product meets the limitations of claims 9 and 11 of the '715 patent;

8. Whether the 1000 mg/20 mg Watson Product meets the limitations of claims 25 and 27 of the '229 patent;

9. Whether the use of the 1000 mg/20 mg Watson Product in accordance with Watson's proposed labeling meets the limitations of claims 16, 18, 25, and 26 of the '967 patent;

10. Whether the 1000 mg/20 mg Watson Product meets the limitations of claims 13 and 15 of the '691 patent;

11. Whether the use of the 1000 mg/20 mg Watson Product in accordance with Watson's proposed labeling meets the limitations of claims 2-5, 11-13, and 21-30 of the '035 patent;

12. Whether the 1000 mg/20 mg Watson Product together with Watson's proposed labeling for the 1000 mg/20 mg Watson Product would induce infringement for the asserted method claims of the '428, '930, '848, '967, and '035 patents;

13. The scope and content of the prior art;

14. The level of ordinary skill in the art;

15. The differences between the inventions claimed in the asserted claims of the patents-in-suit and the prior art;

16. Whether any one of the asserted prior art references individually discloses each of the elements of the claims 2-5 and 11-13 of the '035 patent and the asserted claims of the '428, '930, '848, '715, '229, '967, and '691 patents;

17. Whether the inventions claimed in the asserted claims of the patents-in-suit would have been obvious to a person of skill in the art at the time of the claimed inventions in view of the asserted prior art;

18. Whether the inventions claimed in the asserted claims of the '035 patent would have been an obvious variation of the inventions claimed in the '930, '848, '715, '229, '967, and '691 patents to a person of ordinary skill in the art at the time of invention of the '035 patent;

19. Whether the inventions claimed in the asserted claims of the patents-in-suit produced unexpected results;

20. Whether there exist secondary considerations of nonobviousness of the inventions claimed in the asserted claims of the patents-in-suit, including:

a. Whether there existed at the time of the inventions a long-felt but unmet need satisfied by the inventions claimed in the asserted claims of the patents-in-suit;

b. Whether the inventions claimed in the asserted claims of the patents-in-suit initially were received with skepticism followed by acceptance;

c. Whether there has been third-party praise for the inventions claimed in the asserted claims of the patents-in-suit;

d. Whether others have failed in developing the inventions claimed in the asserted claims of the patents-in-suit;

e. Whether others have copied the inventions claimed in the asserted claims of the patents-in-suit;

f. Whether the inventions claimed in the asserted claims of the patents-in-suit have been licensed;

g. Whether the commercial embodiments of the patents-in-suit are a commercial success; and

h. Whether the commercial success of the embodiments of the patents-in-suit is attributable to the inventions claimed in the patents-in-suit;

21. Whether the patents-in-suit provide adequate written description such that a person of ordinary skill in the art at the time of the invention would understand that the inventors were in possession of the inventions claimed in claim 3 of the ’428 patent, claim 3 of the ’848 patent, claims 2-5, 11-13, 21, and 26-30 of the ’035 patent, and the asserted claims of the ’930, ’715, ’229, ’691, and ’967 patents;

22. Whether the patents-in-suit enable a person of ordinary skill in the art at the time of the invention to practice the inventions claimed in claim 3 of the ’428 patent, claim 3 of the ’848 patent, claims 2-5, 11-13, 21, and 26-30 of the ’035 patent, and the asserted claims of the ’930, ’715, ’229, ’691, and ’967 patents without undue experimentation;

23. Whether the inventor of the ’428 patent subjectively possessed a best mode for practicing the invention claimed in the asserted claims of the ’428 patent, and if so, whether he concealed that best mode;

24. Whether claim 3 of the ’428 patent, claims 2-5, 11-13, 21, and 26-30 of the ’035 patent, and the asserted claims of the ’930, ’848, ’715, ’229, ’967, and ’691 patents would have been insolubly ambiguous to a person of ordinary skill in the art at the time of the invention;

25. Whether Abbott would suffer irreparable injury through the sale of the 500 mg/40 mg Watson Product or 1000 mg/20 mg Watson Product (collectively, “the Watson Products”);

26. Whether the remedies available at law are inadequate to compensate Abbott for its injuries through the sale of any of the Watson Products;

27. Whether the balance of hardships favors enjoining the sale of any of the Watson Products; and

28. Whether the public interest favors enjoining the sale of any of the Watson Products.

EXHIBIT D

EXHIBIT D – DEFENDANT'S STATEMENT OF INTENDED TRIAL PROOFS

Defendant submits the following statements of intended proof setting forth a description of what Defendant intends to prove at trial to support its defenses and counterclaims.

Because Abbott asserts more than 70 different claims from eight patents against six proposed products, it is difficult to provide a brief overview without omitting significant detail. The following statements are therefore not exhaustive, and Defendant reserves the right to prove any matters identified in its pleadings, interrogatory responses, or expert reports.

Defendant also intends to offer proof as to the issues of fact and issues of law identified in this pretrial order. Defendant further intends to offer proof to rebut evidence offered by Abbott. Defendant reserve the right to amend and supplement its statement (and the proofs it intends to offer at trial) in response to any subsequent discovery or changes to Abbott's contentions and other positions.

Defendant incorporates by reference their discovery responses and experts' reports and deposition testimony as though fully set forth herein.

Abbott has asserted certain claims in this case that Defendant's product does not infringe. And all of Abbott's asserted claims are invalid, including for anticipation, obviousness, indefiniteness, failure to comply with the best mode requirement, lack of enablement, failure to comply with the written description requirement, and obviousness-type double patenting.

I. Overview of Non-infringement Proof

Abbott bears the burden of proving infringement. Defendant intends to present evidence rebutting the evidence that Abbott offers in its attempt to prove infringement. Defendant

reserves its right to present appropriate rebuttal evidence in response to the infringement arguments Abbott chooses to present at trial.

This case involves eight patents asserted against two proposed generic tablets. Each accused tablet has a core with 500 mg, 1000 mg of extended release niacin. An immediate-release coating that contains either 20 mg or 40 mg of simvastatin surrounds the core of each accused tablet.

Of the eight patents in suit, seven are directed only to extended release niacin formulations and methods of administering them. Three of the patents in suit, U.S. Patent Nos. 6,080, 428 ("the '428 patent); 6,129,930 ("the '930 patent); and the 7,011,848 ("the '848 patent"), define the claimed formulations by reference to the ingredients used in the formulations and/or the once-daily administration of formulations defined by reference to such ingredients. Two of the patents, U.S. Patent Nos. 6,406,715 ("the '715 patent) and 6,818,229 ("the '229 patent"), define the claimed formulations by reference to how the formulations behave when administered to humans. And the last two extended release niacin patents, U.S. Patent Nos. 6,676,967 ("the '967 patent") and 6,746,691 ("the '691 patent"), define the claimed formulations and methods by reference to the rate at which the formulations release niacin in laboratory dissolution tests.

The asserted claims of the last patent in suit, U.S. Patent No. 6,469,035 ("the '035 patent"), are directed to methods of reducing flushing involving a "pretreatment" regimen with aspirin. These claims further require formulations containing both extended release niacin and a HMGCoA reductase inhibitor, more commonly referred to as a "statin."

Watson seeks to introduce its generic 1000 mg / 20 mg and 500 mg / 40 mg Simcor tablets. All totaled, Abbott asserts various claims against some, but not all, of these two dosage

forms. The following table summarizes which claims of the eight patents are asserted against each of the five dosage forms:

WATSON	**1000 mg / 20 mg**	**500 mg / 40 mg**
'428 patent	1, 3, 5, 6, 8	None
'930 patent	18–21, 25, 27,-29, 51, 115, 133–136, 140, 142–44	None
'848 patent	1, 3, 5, 6, 8	None
'691 patent	13, 15	1, 3
'967 patent	16, 18, 25, 26	None
'229 patent	25, 27	9, 11
'715 patent	9, 11	1, 3, 5
'035 patent	2–5, 11–13, 21–30	None

The Defendant intends to prove the following with respect to each of the above-listed asserted claims:

1. The Defendant's proposed labels do not induce infringement of the asserted claims of the '848 and '930 patents because the labels do not permit the use of Defendant's products to reduce Lp(a).

2. Watson's proposed 500 mg / 40 mg product and its corresponding label does not infringe or induce the infringement of claims 9 and 11 of the '229 Patent.

3. Watson's proposed 1000 mg / 20 mg product does not infringe claims 9 and 11 of the '715 patent or claims 25 and 27 of the '229 patent.

4. Watson's proposed 500 mg / 40 mg product does not infringe claims 1, 3 or 5 of the '715 patent or claims 9 and 11 of the '229 patent.

5. Abbott has failed to demonstrate that claims 9, 11, 17, 19, 25, and 26 of the '229 patent are infringed.

6. Watson's proposed 500 mg / 40 mg product labels do not induce infringement of claims 1, 3, and 5 of the '715 Patent.

7. Abbott has failed to demonstrate that any of defendant's proposed products infringe claims 1, 3, 5, 7, 9, and 11 of the '715 patent.

8. Watson's proposed labels do not induce infringement of claims 2–5, 11–13, and 21–30 of the '035 Patent.

9. Watson's products do not infringe the asserted claims because those products do not meet claimed limitations concerning the absence of certain side effects.

10. Watson's products do not infringe claim 6 of the '428 Patent.

11. Watson's products do not infringe claim 25 of the '930 Patent.

12. Watson's products do not infringe claim 28 of the '930 patent.

13. Watson's' products do not infringe claim 29 of the '930 patent.

14. Watson's products do not infringe claim 140 of the '930 patent.

15. Watson's products do not infringe claim 143 of the '930 patent.

16. Watson's' products do not infringe claim 6 of the '848 patent.

17. Watson's proposed 500/40mg product does not infringe claims 1 or 3 of the '691 patent.

II. Overview of Invalidity Proof

Defendant intends to present evidence at trial that the asserted claims of all of the patents in suit are anticipated by or obvious in view of the prior art, are invalid for failure to comply with Section 112 of the Patent Act, and are invalid for obviousness-type double patenting. Defendant's invalidity charts and experts' reports, setting forth the invalidity defenses asserted as

against each of the patents in suit, are hereby incorporated by reference as though fully set forth herein.

With the exception of claims 20–30 of the ’035 patent, each claim asserted by Abbott is invalid as anticipated under 35 U.S.C. § 102. Specifically, for each of the asserted claims, at least one prior-art reference teaches every claimed limitation. For most claims, in fact, several prior art references independently teach each element.

Defendant intends to prove that, at the time of the purported invention, those of ordinary skill in the art knew that niacin was an effective agent to treat hyperlipidemia because it both lowers bad cholesterol (LDL, TC, Lp(a), and TGs) and increases good cholesterol (HDL). Those of ordinary skill in the art would have also understood the advantages of administering niacin once a day, which was a well-known method of administration before the priority dates for each of the patents-in-suit. Similarly, the prior art suggested administering niacin once-daily during the evening or at night.

Those of ordinary skill in the art would have understood the benefits of extended-release formulations of niacin, such as improving patient compliance by reducing the number of doses per day and minimizing the severity of flushing (particularly because the patient would be asleep during periods of flushing when niacin is administered at night). Further, while the cause of niacin-induced hepatotoxicity was not known, and remains unknown to this day, those of ordinary skill in the art recognized, as confirmed by the prior art literature, that prolonged exposure of niacin to the liver, without an opportunity for the liver to recover, as a potential explanation of why certain extended release niacin products had resulted in hepatotoxicity.

The state of the art concerning extended release formulations of niacin was well developed before the priority date for each of the patents in suit. Those of ordinary skill in the

art knew, for instance, that different HPMC compounds could be, and were, used to prepare niacin formulations that released niacin over a period of time. Numerous prior art references and products would have confirmed for those of skill in the art that certain HPMC compounds could be used to make an extended release formulation of niacin. Those of ordinary skill were also familiar with the use of conventional excipients, such as povidone and stearic acid. The amounts of these ingredients would have been readily determined through the teachings of the aforementioned references, supplemented with the experience possessed by one of ordinary skill in the art, and confirmed with routine experimentation. There was nothing novel, unique, or surprising about using HPMC, stearic acid, or povidone in the manner claimed in the patents in suit—these were conventional ingredients well known to one of ordinary skill. One prior art extended-release niacin product, Slo-Niacin, used HPMC, povidone, and stearic acid. Slo-Niacin was on the market long before the critical dates for the patents-in-suit. Prior art patents and applications further taught the suitability of such excipients for use in extended-release formulations of niacin. In short, the art of extended release niacin formulations, and methods of administering such formulations, was quite crowded as of the priority dates of the patents in suit.

While some of the patents define the formulations by reference to (alleged) features other than the ingredients used in the formulations, the prior art literature and prior art products included formulations that yielded the same outcomes as the claimed inventions when administered to humans, and had the same drug release profiles of the claimed inventions. In addition, any differences between one or more of the prior art products and the claimed inventions are arbitrary, and do not offer any benefits or advantages over the prior art products and formulations.

The limitations concerning the alleged advantages and benefits of the claimed inventions fail to distinguish the alleged inventions over the prior art. Extended release niacin formulations known in the prior art, and known methods of administering those products, are as safe and effective as the claimed inventions. The only benefits of the invention on which Abbott apparently relies are the purported resolution of hepatotoxicity and treatment limiting increases in uric acid and glucose levels. But these were relatively uncommon problems with prior art products and methods. Abbott's claimed invention did not eliminate this risk, and Abbott has failed to identify any reliable evidence demonstrating the superiority of the claimed inventions relative to the prior art. Consequently, the patents-in-suit did not advance the state of the art, and the embodiments of the claimed invention are merely additional members in a long and established line of extended-release niacin products.

Abbott's '035 patent requires pretreating a patient with aspirin to reduce flushing. It was well known in the prior art that administering aspirin to patients shortly before administering niacin reduces flushing. This was well known long before the priority date for each of the patents-in-suit. As with the other claimed subject matter, the applicants for the patents in suit did not develop anything new and useful or otherwise advance the state of the art. The applicants simply followed the teachings in these prior art references when recommending using with aspirin to reduce flushing.

The same holds true for the concomitant administration of niacin and statins, including in a single dosage form containing both drugs. Physicians had been using combination therapy with niacin and statins for many years before the applicants filed their patent applications, as was reported in a myriad of prior art references. Again, the applicants claimed methods that were already well known to those of skill in the art.

With respect to the ’035 patent, the inventors suggest the alleged inventions claimed in the ’035 patent eliminated problems with myopathy and rhabdomyolysis. Once again, however, the claimed inventions did nothing to reduce these problems relative to the prior art. Myopathy and rhabdomyolysis are associated with the administration of *all* HMG-CoA reductase inhibitors, and coating an extended-release niacin formulation with a HMG-CoA reductase inhibitor does not reduce the risk that a patient will develop myopathy and rhabdomyolysis.

With respect to Abbott’s contentions concerning secondary considerations, Defendant intends to prove that the secondary considerations of non-obviousness alleged by Abbott fail to rebut Defendant’s *prima facie* showing of obviousness.

The ’035 patent is also invalid due to obviousness-type double patenting. The inventions claimed in the ’035 patent do not introduce anything that was not already known in the prior art, and the claims of the ’035 patent are merely obvious modifications of the previously filed patents in suit. Defendant will show that the elements of the asserted claims of the ’035 patent that are not required by the claims of the earlier patents were already well known to those of ordinary skill in the art. Specifically, administering an NSAID, such as aspirin, shortly before niacin administration was known in the prior art for decades, and the concomitant administration of niacin and statins was a common practice, as demonstrated by prior art publications concerning many studies involving the concomitant administration of those products. The combination of these drugs into a fixed dosage form was already described in the literature, and would have been nothing more than a ministerial exercise driven by common sense. These steps were nothing more than an obvious modification of the claims of the ’428, ’930, ’848, ’691, and ’967 patents.

The asserted patents are invalid for failing to meet the requirements of Section 112 of the patent act. The patents-in-suit are invalid for failing to provide a proper written description and

failing to enable the claims. Despite providing a very narrow disclosure in the patents-in-suit, the asserted claims are extremely broad. For example, the described embodiments do not eliminate the side effects that the claims purport to resolve. The claims requiring such amelioration are therefore not enabled. Nor does the written description show that the inventors were in possession of technology that reduces those side effects. Similarly, the claims cover many different dosage forms involving many different excipients and dosage strengths. Yet the applications only describe the Niaspan formulations. This deficient disclosure is compounded by the variability of the *in vivo* parameters used by the inventors to describe their purported invention.

Many claims asserted against Defendant'' products are also invalid as indefinite. Specifically, many of the claim limitations are insoluably ambiguous. For example, many claims are directed toward the ability of the claimed methods and formulas to avoid treatment-limiting side effects. The determination of whether a side effect is treatment limiting, however, is made on a case-by-case basis, subject to a doctor's and patient's individual, subjective judgments. Moreover, limitations directed toward *in vivo* parameters fail to define the claimed formulations because the effects vary from patient to patient or over time for a single patient. Additional terms are indefinite, as set forth in Defendant's invalidity contentions, experts' reports, and the Joint Claim Construction Statement.

EXHIBIT E

DEFENDANTS' STATEMENT OF ISSUES OF FACT REMAINING TO BE LITIGATED

To the extent that Defendants' statement of issues of law set forth in Exhibit 5 contains issues of fact, those issues are incorporated herein by reference. Should the Court determine any issue identified by Defendants as an issue of fact to be more appropriately considered an issue of law; Defendants incorporate such issues by reference into their statement of issues of law. By including a fact herein, Defendants do not assume the burden of proof or production with regard to that fact. Nor do Defendants take any position that the resolution of any issues identified in this pleading to be one of fact, rather than one of law.

Defendants' identification of issues of fact that remain to be litigated is based in part on Defendants' understanding of Plaintiffs' arguments concerning infringement and invalidity, which is based on Plaintiffs' interrogatory responses and expert reports.

Any claims Plaintiffs did not raise in their expert reports or their responses to Defendants' interrogatories seeking Plaintiffs' allegations regarding infringement and validity have been waived, and Defendants will not address any such claims.

I. PRIORITY DATES

The issues of fact remaining with respect to Defendants' allegations that the asserted claims of the patents-in-suit are not entitled to critical dates earlier than one year before the filing of each application are as follows:

1. Whether the asserted claims of the '428 patent are entitled to a priority date earlier than one year before the filing date of the '428 patent application.

2. Whether the asserted claims of the '428 patent are entitled to a priority date earlier than the filing date of the '428 patent application under 102(a) and 102(e).

3. Whether the asserted claims of the ‘930 patent are entitled to a priority date earlier than one year before the filing date of the ‘930 patent application.

4. Whether the asserted claims of the ‘930 patent are entitled to a priority date earlier than the filing date of the ‘930 patent application under 102(a) and 102(e).

5. Whether the asserted claims of the ‘848 patent are entitled to a priority date earlier than one year before the filing date of the ‘848 patent application.

6. Whether the asserted claims of the ‘848 patent are entitled to a priority date earlier than the filing date of the ‘848 patent application under 102(a) and 102(e).

7. Whether the asserted claims of the ‘715 patent are entitled to a priority date earlier than one year before the filing date of the ‘715 patent application.

8. Whether the asserted claims of the ‘715 patent are entitled to a priority date earlier than the filing date of the ‘715 patent application under 102(a) and 102(e).

9. Whether the asserted claims of the ‘229 patent are entitled to a priority date earlier than one year before the filing date of the ‘229 patent application.

10. Whether the asserted claims of the ‘229 patent are entitled to a priority date earlier than the filing date of the ‘229 patent application under 102(a) and 102(e).

11. Whether the asserted claims of the ‘691 patent are entitled to a priority date earlier than one year before the filing date of the ‘691 patent application.

12. Whether the asserted claims of the ‘691 patent are entitled to a priority date earlier than the filing date of the ‘691 patent application under 102(a) and 102(e).

13. Whether the asserted claims of the ‘967 patent are entitled to a priority date earlier than one year before the filing date of the ‘967 patent application.

14. Whether the asserted claims of the '967 patent are entitled to a priority date earlier than the filing date of the '967 patent application under 102(a) and 102(e).

15. Whether the asserted claims of the '035 patent are entitled to a priority date earlier than one year before the filing date of the '035 patent application.

16. Whether the asserted claims of the '035 patent are entitled to a priority date earlier than the filing date of the '035 patent application under 102(a) and 102(e).

II. ANTICIPATION

The issues of fact remaining with respect to Defendants' allegations that the asserted claims of the patents-in-suit are anticipated are as follows:

1. Whether claims 1 and 3 of the '428 patent are anticipated expressly or inherently by one or more of the following:

- *Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults*, 148(1) Arch. Intern. Med., 36-69 (1988)
- *Issues in Cholesterol Management: Reappraisal of Niacin*, Upsher-Smith Laboratories Newsletter, (Donald B. Hunninghake, MD ed.), 1-8 (1990)
- Keenan, J.M., et al., *A Clinical Trial of Oat Bran and Niacin in the Treatment of Hyperlipidemia*, 34(4) J. Fam. Prac. 313-19 (1992)
- Nicobid product and associated labeling and guidance, *see*, *e.g.*, Physicians' Desk Reference, Medical Economics Co., Montvale, N.J. (46th ed., 1992);
- Nicobid product and associated labeling and guidance, *see*, *e.g.*, Aventis Pharmaceutical's Nicobid labels

- Slo-Niacin product and associated labeling and guidance, *see, e.g.*, Upsher-Smith's Slo-Niacin labels
- Time Caps extended-release niacin product and labels
- Endurance Products' extended release niacin product and labels
- Country Farms' extended release niacin
- Walgreen's time-release niacin manufactured by Pharmavite and labels
- Leiner Health Products' extended release niacin product and labels
- Forest Pharmaceuticals' "Niac" product and labels
- Niaplus 1998-1990 Physician's Desk Reference
- U.S. Patent No. 5,268,181
- USP Labeling Guidance Revised July 1992

2. Whether claims 5-9 of the '428 patent are anticipated expressly or inherently by each of the following:

- U.S. Patent No. 5,268,181
- Slo-Niacin product and associated labeling and guidance, *see, e.g.*, Upsher-Smith's Slo-Niacin labels
- *Issues in Cholesterol Management: Reappraisal of Niacin,* Upsher-Smith Laboratories Newsletter, (Donald B. Hunninghake, MD ed.), 1-8 (1990)

3. Whether claims 18 and 133 of the '930 patent are anticipated expressly or inherently by the following:

- All anticipatory references listed above at II.1. and II.2.
- U.S. Patent No. 5,126,145

- Slo-Niacin, Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., (47th ed., 1993)
- Nicobid, Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., (47th ed., 1993)
- Morgan J.M. & Capuzzi D.M., *Safe and Effective Treatment of Dyslipidemia by Niaspan™, a New Sustained-Release Niacin* 59(2) Clin. Pharm. & Therapeut., 166 (1996)
- EP Patent Application 0643965

4. Whether claims 51 and 115 of the '930 patent are anticipated expressly or inherently by the following:

- All anticipatory references listed above at II.1. and II.2.
- Slo-Niacin, Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., (47th ed., 1993)
- Nicobid, Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., (47th ed., 1993)
- Morgan J.M. & Capuzzi D.M., *Safe and Effective Treatment of Dyslipidemia by Niaspan™, a New Sustained-Release Niacin* 59(2) Clin. Pharm. & Therapeut., 166 (1996)
- EP Patent Application 0643965

5. Whether claims 19-21, 24-29, 134-136, 139-144 of the '930 patent are anticipated expressly or inherently by the following:

- All anticipatory references listed above at II.2.
- U.S. Patent No. 5,126,145
- Slo-Niacin, Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., (47th ed., 1993)

- Morgan J.M. & Capuzzi D.M., *Safe and Effective Treatment of Dyslipidemia by Niaspan™, a New Sustained-Release Niacin* 59(2) Clin. Pharm. & Therapeut., 166 (1996)
- EP Patent Application 0643965

6. Whether claims 1 and 3 of the '848 patent are anticipated expressly or inherently by the following:

- All anticipatory references listed above at II.1.
- Slo-Niacin, Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., (47th ed., 1993)
- Nicobid, Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., (47th ed., 1993)
- Morgan, J.M., et al., *Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial*, 1(3) J. Cardiovasc. Pharmacol. Therapeut., 195-202 (1996)
- Morgan J.M. & Capuzzi D.M., *Safe and Effective Treatment of Dyslipidemia by Niaspan™, a New Sustained-Release Niacin* 59(2) Cardiovasc. Pharmacol. Therapeut., 166 (1996)
- EP Patent Application 0643965

7. Whether claims 5-9 of the '848 patent are anticipated expressly or inherently by the following:

- All anticipatory references listed above at II.2.
- Slo-Niacin, Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., (47th ed., 1993)

- Morgan, J.M., et al., *Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial*, 1(3) J. Cardiovasc. Pharmacol. Therapeut., 195-202 (1996)
- Morgan J.M. & Capuzzi D.M., *Safe and Effective Treatment of Dyslipidemia by Niaspan™, a New Sustained-Release Niacin* 59(2) Clin. Pharm. & Therapeut., 166 (1996)
- EP Patent Application 0643965

8. Whether claims 1, 3, 5, 7, 9, and 11 of the '715 patent are anticipated expressly or inherently by the following:

- Application Serial No. 08/814,974 (corresponding to the '930 patent)
- Morgan, J.M., et al., *Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial*, 1(3) J. Cardiovasc. Pharmacol. Therapeut., 195-202 (1996)
- Morgan J.M. & Capuzzi D.M., *Safe and Effective Treatment of Dyslipidemia by Niaspan™, a New Sustained-Release Niacin* 59(2) Cardiovasc. Pharmacol. Therapeut., 166 (1996)
- U.S. Patent No. 5,126,145
- U.S. Patent No. 5,268,181
- Slo-Niacin product and associated labeling and guidance, *see, e.g.* Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., 2492 (47th ed., 1993)
- Slo-Niacin product and associated labeling and guidance, *see, e.g.*, Upsher-Smith's Slo-Niacin labels
- Nicobid product and associated labeling and guidance, *see, e.g.*, Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., 2026; (p. 1846, 46th ed., 1992)

- Nicobid product and associated labeling and guidance, *see, e.g.,* Aventis Pharmaceuticals Nicobid labels

9. Whether claims 9, 11, 17, 19, 25, and 27 of the '229 patent are anticipated expressly or inherently by the following:

- Application Serial No. 08/814,974 (corresponding to the '930 patent)
- Morgan, J.M., et al., *Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial,* 1(3) J. Cardiovasc. Pharmacol. Therapeut., 195-202 (1996)
- Morgan J.M. & Capuzzi D.M., *Safe and Effective Treatment of Dyslipidemia by Niaspan™, a New Sustained-Release Niacin* 59(2) Cardiovasc. Pharmacol. Therapeut., 166 (1996)
- U.S. Patent No. 5,126,145
- U.S. Patent No. 5,268,181
- Slo-Niacin product and associated labeling and guidance, *see, e.g.* Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., 2492 (47th ed., 1993);
- Slo-Niacin product and associated labeling and guidance, *see, e.g.*, Upsher-Smith's Slo-Niacin labels

10. Whether claims 1, 3, 13, and 15 of the '691 patent are anticipated expressly or inherently by the following:

- Application Serial No. 08/814,974 (corresponding to the '930 patent)
- Morgan, J.M., et al., *Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial,* 1(3) J. Cardiovasc. Pharmacol. Therapeut., 195-202 (1996)

- Morgan J.M. & Capuzzi D.M., *Safe and Effective Treatment of Dyslipidemia by Niaspan™, a New Sustained-Release Niacin* 59(2) Cardiovasc. Pharmacol. Therapeut., 166 (1996)
- U.S. Patent No. 5,126,145
- U.S. Patent No. 5,268,181
- Slo-Niacin product and associated labeling and guidance, *see, e.g.* Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., (47th ed., 1993)
- Slo-Niacin product and associated labeling and guidance, *see, e.g.*, Upsher-Smith's Slo-Niacin labels
- Products listed in Table 5A and 5B of the '691 patent at cols. 11-12, Table 7

11. Whether claims 16, 18, 25, and 26 of the '967 patent are anticipated expressly or inherently by the following:

- Application Serial No. 08/814,974 (corresponding to the '930 patent)
- U.S. Patent No. 5,268,181
- U.S. Patent No. 5,126,145
- Morgan, J.M., et al., *Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial*, 1(3) J. Cardiovasc. Pharmacol. Therapeut., 195-202 (1996)
- Morgan J.M. & Capuzzi D.M., *Safe and Effective Treatment of Dyslipidemia by Niaspan™, a New Sustained-Release Niacin* 59(2) Cardiovasc. Pharmacol. Therapeut., 166 (1996)

12. Whether claims 2-5, 11-13 of the '035 patent are anticipated expressly or inherently by the following:

- *Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults*, 148(1) Arch. Intern. Med., 36-69 (1988).

III. OBVIOUSNESS

The issues of fact remaining with respect to Defendants' allegations that the asserted claims of the patents-in-suit (claims 1, 3, 5-9 of the '428 patent, claims 18-21, 24-29, 51, 115, 133-136, 139-144 of the '930 patent, claims 1, 3, 5-9 of the '848 patent, claims 1, 3, 5, 7, 9, 11 of the '715 patent, claims 9, 11, 17, 19, 25, 27 of the '229 patent, claims 16, 18, 25, 26 of the '967 patent, claims 1, 3, 13, 15 of the '691 patent, claims 2-5, 11-13, 21-30 of the '035 patent) are obvious are as follows:

1. Whether the subject matter of the asserted claims of the patents-in-suit would have been obvious to a person of ordinary skill in the art under 35 U.S.C. § 103 at the time the alleged invention was made.

A. Level of Ordinary Skill in the Art

1. What the qualifications and knowledge of a person of ordinary skill in the art pertinent to the asserted claims of the patents-in-suit were at the time of the alleged inventions of the asserted claims of the patents-in-suit.

B. The Scope and Content of the Prior Art

1. The scope and content of the prior art as of the priority dates[1] for the alleged inventions of the asserted claims of the patents-in-suit.

[1] *See* Section I. above.

C. The Differences Between the Claimed Invention and the Prior Art[2]

1. Whether any differences between the subject matter of claims 1, 3, 5-9 of the '428 patent and the prior art are such that the patented subject matter would have been obvious to a person having ordinary skill in the art as of the priority date for such alleged inventions, and in view of:

- All anticipatory references cited above at II.1. and II.2.;
- U.S. Patent No. 5,126,145;
- Lavie C.J., et al., *Marked Benefit with Sustained-Release Niacin Therapy in Patients with "Isolated" Very Low Levels of High-Density Lipoprotein Cholesterol and Coronary Artery Disease*, 69 Am. J. Cardiol., 1083-85 (1992);
- Squires R.W., *Low-Dose, Time-Release Nicotinic Acid: Effects in Selected Patients With Low Concentrations of High-Density Lipoprotein Cholesterol*, 67(9) Mayo Clin Proc 855-60 (1992);
- Robert H. Knopp et al., *Contrasting Effects of Unmodified and Time-Release Forms of Niacin on Lipoproteins in Hyperlipidemic Subjects: Clues to Mechanism of Action of Niacin*, 34(7) Metabolism, 642-650 (1985);
- Joseph M. Keenan et al., *Niacin Revisited: A Randomized, Controlled Trial of Wax-Matrix Sustained-Release Niacin in Hypercholesterolemia*, 151(7) Arch. Intern. Med., 1424-1432 (1991);

[2] Defendants explicitly incorporate by reference any additional prior art references not specifically cited herein that were reviewed and cited by Dr. Joseph Keenan, Dr. William F. Elmquist, Dr. Michael B. Maurin in either their opening expert reports dated August 19, 2011, supplemental reports dated September 19, 2011, rebuttal reports dated September 19, 2011, and reply expert reports dated October 17, 2011, or provided or disclosed during their depositions on November 10-11, 2011, November 3-4, 2011, or October 27-28, 2011 respectively, in support of their obviousness defenses.

- Alderman J.D., et al., *Effect of a Modified, Well-Tolerated Niacin Regimen on Serum Total Cholesterol, High Density Lipoprotein Cholesterol and the Cholesterol to High Density Lipoprotein Ratio,* 64 Am. J. Cardiol., 725-29 (1989);
- Luria M.H., *Effect of Low-Dose Niacin on High-Density Lipoprotein Cholesterol and Total Cholesterol/High-Density Lipoprotein Cholesterol Ratio,* 148(11) Arch. Intern. Med., 2493-95 (1988);
- Nicobid, Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., (47th ed., 1993);
- Slo-Niacin, Physicians' Desk Reference, Medical Economics Co., Montvale, N.J., (47th ed., 1993);
- United States Pharmacopeia Dispensing Information ("USPDI"), 1739-1740 (9th ed., 1989)
- Schlierf, G. & Hess, G., *Inhibition of Carbohydrate-induced Hypertriglyceridemia by Nicotinic Acid,* 3(2) Artery 174-79 (1977);
- Guenter Schlierf and E. Dorow, *Diurnal Patterns of Triglycerides, Free Fatty Acids, Blood Sugar, and Insulin during Carbohydrate-Induction in Man and Their Modification by Nocturnal Suppression of Lipolysis,* 52:3 J. Clin. Invest., 732-740 (1973);
- Miettinen T.A., *Diurnal Variation of Cholesterol Precursors Squalene and Methyl Sterols in Human Plasma Lipoproteins,* 23(3) J. Lipid Res. 466-73 (1982);
- Carlson, et al., Pronounced lowering of serum levels of lipoprotein Lp(a) in hyperlipidemic subjects treated with nicotinic acid, 226 J. Intern. Med., 271-276 (1989);
- Illingworth, et al., Comparative Effects of Lovastatin and Niacin in Primary Hypercholesterolemia, 154 Arch. Intern. Med., 1586-1595 (1994);

- Henkin, Yaakov, et al., *Niacin Revisited: Clinical Observations on an Important but Underutilized Drug*, 91 The Amer. J Med. 239, 242-43 (1991);
- Rader, J, *et al.*, *Hepatic Toxicity of Unmodified and Time-Release Preparations of Niacin*, 92 Amer. J Med., 77-81 (1992);
- 124,392 Patent Application (now abandoned, parent to '428);
- Byrd C. and Mowrey K.A., *Lipid and transaminase concentrations after formulary conversion of Niaspan to Slo-Niacin*, 267(23) Am. J. Health Syst. Pharm., 2038-42 (2010);
- Knopp R.H., *The SLIM study: Slo-Niacin and Atorvastatin Treatment of Lipoproteins and Inflammatory Markers in Combined Hyperlipidemia*, 3 J. Clin. Lipidology, 167-78 (2009);
- Gray D.R., et al., *Efficacy and Safety of Controlled-Release Niacin in Dyslipoproteinemic Veterans*, 121(4) Ann. Intern.Med., 252-58 (1994);
- Davignon J., et al., *Comparative Efficacy and Safety of Pravastatin, Nicotinic Acid and the Two Combined in Patients with Hypercholesterolemia*, 73(5) Am. J. Cardiol., 339-45 (1994);
- Pasternak R.C., et al., *Effect of Combination Therapy with Lipid-Reducing Drugs in Patients with Coronary Heart Disease and "Normal" Cholesterol Levels*, 125(7) Ann. Intern.Med., 529-40 (1996);
- Country Farms' extended release niacin;
- Pharmacy Benefits Management-Medical Advisory Panel-VISN Pharmacist Executives Ez-Minutes, vol. 9, issue 1 (November 2010-January 2011);
- U.S. Patent Nos. 4,369,172;

- U.S. Patent Nos. 4,389,393;
- REMINGTON'S PHARMACEUTICAL SCIENCES, 862, 1015-16 (Mack Publishing Co. 17th ed. 1985);
- An Encyclopedia of Chemicals, Drugs, and Biologicals. In: The Merck Index 11 ed., 1461-1462 (1989);
- U.S. Patent No. 5,000,962;
- The Dow Chemical Company, Formulation for Controlled Release with Methocel Cellulose Ethers (1987);
- Aulton M., Pharmaceutics: The Science of Dosage Form Design. Churchill Livingstone; 1994, 1988;
- Patel W.D., Handbook of Pharmaceutical Excipients. 234-239 (1986);
- Han W., Handbook of Pharmaceutical Excipients. (American Pharmaceutical Association) 173-175 (1986);
- Schwartz T., Handbook of Pharmaceutical Excipients. (American Pharmaceutical Association) 298-300 (1986);
- Christenson, N.A., et al., *Nicotinic Acid Treatment of Hypercholesterolemia*, 177(8) JAMA, 546-550 (1961);
- Dalton and Robert S. Berry, *Hepatotoxicity Associated with Sustained-Release Niacin*, 93(1) Am. J. Med., 102-104 (1992);
- the general knowledge and common sense of those of ordinary skill in the art regarding methods of administration of extended release niacin;
- the general knowledge and common sense of those of ordinary skill in the art regarding extended release drug formulation development.

2. Whether any differences between the subject matter patented in claims 18-21, 24-29, 51, 115, 133-136, 139-144 of the '930 patent and the prior art are such that the patented subject matter would have been obvious to a person having ordinary skill in the art as of the priority date for such alleged inventions, and in view of:

- All references cited above at III.C.1;
- All references cited above at II.3 through II.5;
- the general knowledge and common sense of those of ordinary skill in the art regarding methods of administration of extended release niacin;
- the general knowledge and common sense of those of ordinary skill in the art regarding extended release drug formulation development.

3. Whether any differences between the subject matter patented in claims 1, 3, 5-9 of the '848 patent and the prior art are such that the patented subject matter would have been obvious to a person having ordinary skill in the art as of the priority date for such alleged inventions, and in view of:

- All references cited above at III.C.1;
- All references cited above at II.6 through II.7;
- the general knowledge and common sense of those of ordinary skill in the art regarding methods of administration of extended release niacin;
- the general knowledge and common sense of those of ordinary skill in the art regarding extended release drug formulation development.

4. Whether any differences between the subject matter patented in claims 1, 3, 5, 7, 9, 11 of the '715 patent and the prior art are such that the patented subject matter would have

been obvious to a person having ordinary skill in the art as of the priority date for such alleged inventions, and in view of:

- All references cited above at III.C.1;
- All references cited above at II.8;
- EP Patent Application 0643965;
- the general knowledge and common sense of those of ordinary skill in the art regarding methods of administration of extended release niacin;
- the general knowledge and common sense of those of ordinary skill in the art regarding extended release drug formulation development.

5. Whether any differences between the subject matter patented in claims 9, 11, 17, 19, 25, 27 of the ‘229 patent and the prior art are such that the patented subject matter would have been obvious to a person having ordinary skill in the art as of the priority date for such alleged invention, and in view of:

- All references cited above at III.C.1;
- All references cited above at II.9;
- EP Patent Application 0643965;
- the general knowledge and common sense of those of ordinary skill in the art regarding methods of administration of extended release niacin;
- the general knowledge and common sense of those of ordinary skill in the art regarding extended release drug formulation development.

6. Whether any differences between the subject matter patented in claims 1, 3, 13, 15 of the ‘691 patent and the prior art are such that the patented subject matter would have been

obvious to a person having ordinary skill in the art as of the priority date for such alleged inventions, and in view of:

- All references cited above at III.C.1;
- All references cited above at II.10;
- EP Patent Application 0643965;
- the general knowledge and common sense of those of ordinary skill in the art regarding methods of administration of extended release niacin;
- the general knowledge and common sense of those of ordinary skill in the art regarding extended release drug formulation development.

7. Whether any differences between the subject matter patented in claims 16, 18, 25 and 26 of the ‘967 patent and the prior art are such that the patented subject matter would have been obvious to a person having ordinary skill in the art as of the priority date for such alleged inventions, and in view of:

- All references cited above at III.C.1;
- All references cited above at II.11;
- EP Patent Application 0643965;
- the general knowledge and common sense of those of ordinary skill in the art regarding methods of administration of extended release niacin;
- the general knowledge and common sense of those of ordinary skill in the art regarding extended release drug formulation development.

8. Whether any differences between the subject matter patented in claims 2-5, 11-13, 21-30 of the ’035 patent and the prior art are such that the patented subject matter would have

been obvious to a person having ordinary skill in the art as of the priority date for such alleged inventions:

- All references cited above at III.C.1-7;
- All references cited above at II.12;
- Gardner S.F., et al., *Combination Therapy with Low-Dose Lovastatin and Niacin Is as Effective as Higher-Dose Lovastatin*, 16(3) Pharmacotherapy, 419-23 (1996);
- O'Keefe J.H., et al., *Effects of Pravastatin With Niacin or Magnesium on Lipid Levels and Postprandial Lipidemia*, 76 Am. J. Cardiol., 480-84 (1995);
- Stein, E.A., et al., *Efficacy and Tolerability of Low-dose Simvastatin and Niacin, Alone and in Combination, in Patients With Combined Hyperlipidemia: A Prospective Trial* 1(2) J. Cardiovasc. Pharmacol. Therapeut., 107-16 (1996);
- Brown B.G., et al., *Simvastatin and Niacin, Antioxidant Vitamins, or the Combination for the Prevention of Coronary Disease*, 345(22) NEJM, 1583-1592 (2001);
- Brown B.G., et al., *Moderate Dose, Three-Drug Therapy with Niacin, Lovastatin, and Colestipol to Reduce Low-Density Lipoprotein Cholesterol <100 mg/dl in Patients with Hyperlipidemia and Coronary Artery Disease*, 80 Am. J. Cardiol., 111-115 (1997);
- Yasuhi Saito, et al., *Comparison Between Morning and Evening Doses of Simvastatin in Hyperlipidemic Subjects: A Double-Blind Comparative Study*, 11(4) Aterioscler. Thromp., 816-826 (1991);
- U.S. Patent No. 5,260,305;
- December 19, 1991, Lovastatin Package Insert;
- April 27, 2000, Simvastatin Package Insert;

- Lieberman, Compress Tablets by Wet Granulation. In: *Pharmaceutical Dosage Forms*. Vol. 1 (Marcek Dekkar) 179-99 (1989);
- Figge H.L., et al., *Comparison of Excretion of Nicotinuric Acid After Ingestion of Two Controlled Release Nicotinic Acid Preparations in Man*, 28(12) J. Clin. Pharmacol., 1136-1140 at 1137 (1988);
- Whelan A.M., et al., *The Effect of Aspirin on Niacin-Induced Cutaneous Reactions*, 34(2) J. Fam. Prac., 34(2): 165-168 at 165-166 (1992);
- U.S. Patent No. 5,773,453;
- the general knowledge and common sense of those of ordinary skill in the art regarding methods of administration of extended release niacin;
- the general knowledge and common sense of those of ordinary skill in the art regarding extended release drug formulation development.

D. <u>Secondary Considerations of Nonobviousness</u>

1. Whether Plaintiffs have carried their burden of showing the existence of any secondary considerations of non-obviousness with respect to the asserted claims of the patents-in-suit, that such secondary considerations have a nexus to the invention(s) of those claims, and that such secondary considerations are of sufficient weight to override a *prima facie* case of obviousness.

2. Whether the alleged inventions of the asserted claims of the patents-in-suit are unexpectedly superior to the prior art with respect to the frequency with which those products cause elevations in liver enzymes to an extent that requires discontinuation of therapy, and that any such unexpected superior property is of sufficient weight to override a *prima face* case of obviousness.

3. Whether the alleged inventions of the asserted claims of the patents-in-suit are unexpectedly superior to the prior art with respect to the frequency with which those products cause elevations in glucose levels to an extent that requires discontinuation of therapy, and that any such unexpected superior property is of sufficient weight to override a *prima face* case of obviousness.

4. Whether the alleged inventions of the asserted claims of the patents-in-suit are unexpectedly superior to the prior art with respect to the frequency with which those products cause elevations in uric acid levels to an extent that requires discontinuation of therapy, and that any such unexpected superior property is of sufficient weight to override a *prima face* case of obviousness.

5. Whether the alleged inventions of the asserted claims of the patents-in-suit are unexpectedly superior to the prior art with respect to the frequency with which those products cause myopathy or rhabdomyolysis, and that any such unexpected superior property is of sufficient weight to override a *prima face* case of obviousness.

6. Whether the alleged inventions of the asserted claims of the patents-in-suit are unexpectedly superior to the prior art with respect to the frequency with which those products cause myopathy and/or muscle aching and weakness when administered in combination with a statin, and that any such unexpected superior property is of sufficient weight to override a *prima face* case of obviousness.

7. Whether Plaintiffs have carried their burden of showing that the alleged inventions of the asserted claims of the patents-in-suit are a commercial success, that any such commercial success has a nexus to the asserted claims of the patents in suit and is not the result of factors such as marketing and advertising efforts or properties or features that were already

known in the prior art, and that any such commercial success is of sufficient weight to override a *prima facie* case of obviousness.

8. Whether Plaintiffs have carried their burden of showing that the alleged inventions of the asserted claims of the patents-in-suit have met a long-felt but unsolved need for a niacin therapy that provided the therapeutic benefits of immediate release niacin while avoiding the side effects associated with immediate release and sustained release forms of niacin, and that any such long-felt but unsolved need is of sufficient weight to override a *prima facie* case of obviousness.

9. Whether Plaintiffs have carried their burden of showing that, prior to the invention date of the asserted claims of the patents-in-suit, others tried and failed to produce an extended release niacin product that was as effective as immediate release niacin in treating patients with lipid disorders, but minimized the flushing associated with immediate release niacin without causing increases in liver enzyme levels, glucose levels, and uric acid levels, to an extent that requires discontinuation of treatment, and that any such failure of others is of sufficient weight to override a *prima facie* case of obviousness.

10. Whether Plaintiffs have carried their burden of showing that, prior to the invention date of the asserted claims of the patents-in-suit, others tried and failed to produce an extended release niacin plus statin product that did not cause hepatotoxicity or cause elevations in glucose and uric acid levels to an extent that required discontinuation of treatment, and that did not cause myopathy and rhabdomyolysis, while matching the efficacy of immediate release niacin, and that any such failure of others is of sufficient weight to override a *prima facie* case of obviousness.

11. Whether Plaintiffs have carried their burden of showing that others expressed skepticism regarding whether the alleged inventions of the asserted claims of the patents-in-suit would serve their intended purpose and that any such skepticism is of sufficient weight to override a *prima facie* case of obviousness.

12. Whether Plaintiffs have carried their burden of showing that the alleged inventions of the asserted claims of the patents-in-suit have received any acclaim, and that any such acclaim is of sufficient weight to override a *prima facie* case of obviousness.

13. Whether Plaintiffs have carried their burden of showing that others have copied the alleged inventions of the asserted claims of the patents-in-suit to such a significant degree as to override a *prima facie* case of obviousness, including in light of the unique regulatory framework under which ANDAs for generic drug products are filed.

14. Whether Niaspan, Advicor, and Simcor are covered by all of the asserted claims of the patents-in-suit.

IV. BEST MODE

The issues of fact remaining with respect to Defendants' allegations that the asserted claims of the '428 patent are invalid for failure to satisfy the best mode requirement are as follows:

1. Whether claims 1, 3, and 5-9 of the '428 patent are invalid for failure to meet the best mode requirement under 35 U.S.C. § 112 for failing to disclose the best mode known to the applicant at the time he filed his patent application.

2. Whether the formulation Mr. Bova finalized and used in the clinical trials in the NDA for Niaspan, which was filed prior to the application that resulted in the '428 patent, was part of his preferred mode of the claimed invention.

V. WRITTEN DESCRIPTION/ ENABLEMENT

The issues of fact remaining with respect to Defendants' allegations that the asserted claims of the patents-in-suit are invalid for lack of an adequate written description and/or enablement under 35 U.S.C. § 112, ¶1 are as follows:

1. Whether a person of ordinary skill in the art would have believed the inventors to have been in possession of the full scope of the asserted claims of the '428, '848, '930, '715, '229, '691, '967, and '035 patents.

2. Whether a person of ordinary skill in the art would have believed the inventors to have enabled the full scope of the asserted claims of the '428, '848, '930, '715, '229, '691, '967, and '035 patents.

VI. INDEFINITENESS

The issues of fact remaining with respect to Defendants' allegations that the asserted claims of the patents-in-suit are indefinite and therefore invalid are as follows:

1. Whether the claims 3, 7, and 11 of the '715 patent are indefinite and thus invalid under 35 U.S.C. § 112, ¶2 for impermissibly reciting both composition and method limitations in the same claim.

2. Whether claim 3 of the '428 patent, claims 1 and 3 of the '848 patent, claims 18, 51, 115, 133 of the '930 patent, claims 1, 5, and 9 of the '715 patent, claims 9, 17, and 25 of the '229 patent, claims 1 and 13 of the'691 patent, claim 16 of the '967 patent, and claims 1 and 21 of the '035 patent, and any claims depending from those claims, are indefinite and thus invalid under 35 U.S.C. § 112, ¶2 because they are insolubly ambiguous.

VII. OBVIOUSNESS TYPE DOUBLE PATENTING

The issues of fact remaining with respect to Defendants' allegations that asserted claims 2-5, 11-13, and 21-30 of the '035 patent are invalid under the doctrine of obviousness type double patenting based upon the '930 patent, '848 patent, '715 patent, '229 patent, '691 patent, and '967 patent are as follows:

1. Whether claims 2-5, 11-13, and 21-30 of the '035 patent are invalid under the doctrine of obviousness type double patenting based upon 35 U.S.C. § 101 because the asserted claims of the '035 patent are mere obvious modifications of the claims of the '930, '848, '715, '229, '691, and '967 patents.

VIII. NONINFRINGEMENT

The issues of fact remaining with respect to Defendants' allegations that asserted claims of the patents-in-suit are not infringed are as follows:

1. Whether the Plaintiffs satisfied their burden of proving Defendants' proposed products and methods of administering the same set forth in the associated product labels would infringe the asserted claims of the patents-in-suit.

EXHIBIT F

EXHIBIT F – ABBOTT'S STATEMENT OF THE ISSUES OF LAW THAT REMAIN TO BE LITIGATED

I. Short Summary of Issues of Law

A. Claim Construction

1. The meaning of certain disputed claim terms in the patents-in-suit.

B. Infringement

1. Whether Watson's submission of ANDA No. 20-0601 and proposed 500 mg/40 mg extended release niacin/simvastatin product infringe claims 1, 3, and 5 of the '715 patent; claims 9 and 11 of the '229 patent; claims 1 and 3 of the '691 patent; and

2. Whether Watson's submission of ANDA No. 20-0601 and proposed 1000 mg/20 mg extended release niacin/simvastatin product infringe, or would induce others to infringe, claims 1, 3, 5, 6, and 8 of the '428 patent; claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the '930 patent; claims 1, 3, 5, 6, and 8 of the '848 patent; claims 9 and 11 of the '715 patent; claims 25 and 27 of the '229 patent; claims 13 and 15 of the '691 patent; claims 16, 18, 25, and 26 of the '967 patent; and claims 2-5, 11-13, and 21-30 of the '035 patent.

C. Invalidity

1. Anticipation

a) Whether claims 1, 3, 5, 6, and 8 of the '428 patent are anticipated under 35 U.S.C. § 102;

b) Whether claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the '930 patent are anticipated under 35 U.S.C. § 102;

c) Whether claims 1, 3, 5, 6, and 8 of the ’848 patent are anticipated under 35 U.S.C. § 102;

d) Whether claims 1, 3, 5, 9, and 11 of the ’715 patent are anticipated under 35 U.S.C. § 102;

e) Whether claims 9, 11, 25, and 27 of the ’229 patent are anticipated under 35 U.S.C. § 102;

f) Whether claims 1, 3, 13, and 15 of the ’691 patent are anticipated under 35 U.S.C. § 102;

g) Whether claims 16, 18, 25, and 26 of the ’967 patent are anticipated under 35 U.S.C. § 102; and

h) Whether claims 2-5 and 11-13 of the ’035 patent are anticipated under 35 U.S.C. § 102.

2. Obviousness

a) Whether claims 1, 3, 5, 6, and 8 of the ’428 patent are obvious under 35 U.S.C. § 103;

b) Whether claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the ’930 patent are obvious under 35 U.S.C. § 103;

c) Whether claims 1, 3, 5, 6, and 8 of the ’848 patent are obvious under 35 U.S.C. § 103;

d) Whether claims 1, 3, 5, 9, and 11 of the ’715 patent are obvious under 35 U.S.C. § 103;

e) Whether claims 9, 11, 25, and 27 of the ’229 patent are obvious under 35 U.S.C. § 103;

f) Whether claims 1, 3, 13, and 15 of the ’691 patent are obvious under 35 U.S.C. § 103;

g) Whether claims 16, 18, 25, and 26 of the ’967 patent are obvious under 35 U.S.C. § 103; and

h) Whether claims 2-5, 11-13, and 21-30 of the ’035 patent are obvious under 35 U.S.C. § 103.

3. Indefiniteness

a) Whether claim 3 of the ’428 patent is invalid as indefinite under 35 U.S.C. § 112;

b) Whether claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the ’930 patent are invalid as indefinite under 35 U.S.C. § 112;

c) Whether claims 1, 3, 5, 6, and 8 of the ’848 patent are invalid as indefinite under 35 U.S.C. § 112;

d) Whether claims 1, 3, 5, 9, and 11 of the ’715 patent are invalid as indefinite under 35 U.S.C. § 112;

e) Whether claims 9, 11, 25, and 27 of the ’229 patent are invalid as indefinite under 35 U.S.C. § 112;

f) Whether claims 1, 3, 13, and 15 of the ’691 patent are invalid as indefinite under 35 U.S.C. § 112;

g) Whether claims 16, 18, 25, and 26 of the ’967 patent are invalid as indefinite under 35 U.S.C. § 112; and

h) Whether claims 2-5, 11-13, 21, and 26-30 of the ’035 patent are invalid as indefinite under 35 U.S.C. § 112.

4. Enablement

a) Whether claim 3 of the ’428 patent is enabled under 35 U.S.C. § 112;

b) Whether claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the ’930 patent are enabled under 35 U.S.C. § 112;

c) Whether claim 3 of the ’848 patent is enabled under 35 U.S.C. § 112;

d) Whether claims 1, 3, 5, 9, and 11 of the ’715 patent are enabled under 35 U.S.C. § 112;

e) Whether claims 9, 11, 25, and 27 of the ’229 patent are enabled under 35 U.S.C. § 112;

f) Whether claims 1, 3, 13, and 15 of the ’691 patent are enabled under 35 U.S.C. § 112;

g) Whether claims 16, 18, 25, and 26 of the ’967 patent are enabled under 35 U.S.C. § 112; and

h) Whether claims 2-5, 11-13, 21, and 26-30 of the ’035 patent are enabled under 35 U.S.C. § 112.

5. Written Description

a) Whether claim 3 of the ’428 patent is invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

b) Whether claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the ’930 patent are invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

c) Whether claim 3 of the ’848 patent is invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

d) Whether claims 1, 3, 5, 9, and 11 of the ’715 patent are invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

e) Whether claims 9, 11, 25, and 27 of the ’229 patent are invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

f) Whether claims 1, 3, 13, and 15 of the ’691 patent are invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

g) Whether claims 16, 18, 25, and 26 of the ’967 patent are invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112; and

h) Whether claims 2-5, 11-13, 21, and 26-30 of the ’035 patent are invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112.

6. Best Mode

a) Whether claims 1, 3, 5, 6, and 8 of the '428 patent are invalid for failure to disclose the best mode of invention under 35 U.S.C. § 112.

7. Obviousness-Type Double Patenting

a) Whether claims 2-5, 11-13, and 21-30 of the '035 patent are invalid for obviousness-type double patenting in view of the claims of the '930, '848, '715, '229, '967, and '691 patents.

II. The Legal Standards Pertaining To The Issues of Law To Be Tried

A. Claim Construction

The construction of claim terms is a matter of law, and a threshold issue that must be addressed prior to an analysis of infringement and validity. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc). As a threshold legal issue that informs the Court's analysis of the issues for trial, the parties will address the construction of certain disputed claim terms during the pretrial conference on January 3, 2012.

To construe a patent claim term, the Court should consider the claim language, specification, and prosecution history. *Id.* This "intrinsic record" is the most important source of evidence in claim construction. *See e.g., Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed. Cir. 1997).

The claims of a patent define the invention, and it is "an evasion of the law[] to construe [claims] in a manner different from the plain import of [their] terms. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation omitted). Claim terms are

generally given their "ordinary and customary meaning," defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1312-13. "The asserted claims can be assigned a narrower scope only if there is some indication in the patent or prosecution history that the term [at issue] was meant to have a more restrictive meaning . . . ." *Saunders Group, Inc. v. Comfortrac, Inc.*, 492 F.3d 1326, 1331 (Fed. Cir. 2007) (citing *Phillips*, 415 F.3d at 1316).

Although claim construction begins with the words of the claims, the claims do not stand alone, but rather are part of "a fully integrated written instrument." *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 978). Accordingly, the claims must be read in view of the patent specification for appropriate context. *Id.*; *Markman*, 52 F.3d at 979 (the specification "may act as a sort of dictionary, which explains the invention and may define terms used in the claims"). The claim construction that "stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316 (internal quotation omitted).

Claims ordinarily should be read so that they include the embodiments described in the patent. A "construction that excludes all of the embodiments of an invention is 'rarely, if ever, correct.'" *Nellcor Puritan Bennett, Inc. v. Masimo Corp.*, 402 F.3d 1364, 1368 (Fed. Cir. 2005) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996)); *see also Oatery Co. v. IPS Corp.*, 514 F.3d 1271, 1277 (Fed. Cir. 2008) (same). A construction that excludes the preferred embodiment is disfavored and requires highly persuasive evidentiary support. *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1377 (Fed. Cir. 2005); *Vitronics*, 90 F.3d at 1583.

However, it is equally fundamental that it is improper to limit a patent claim to the examples or embodiments described in the specification. *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904, 906 (Fed. Cir. 2004); *see also Fuji Photo Film, Co. v. ITC*, 386 F.3d 1095, 1106 (Fed. Cir. 2004) (claim terms are not limited to particular examples provided in the specification unless the specification contains a "clear indication" of such limitation). The Federal Circuit has "repeatedly warned" that, even when the specification "describes very specific embodiments," it is error to "confin[e] the claims to those embodiments." *Phillips*, 415 F.3d at 1323.

Likewise, the Federal Circuit has regularly cautioned that courts, should not "import limitations" into claims from the specification by "confining claims to [particular] embodiments." *Phillips*, 415 F.3d at 1323; *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1370 (Fed. Cir. 2008) ("[T]his court will not at any time import limitations from the specification into the claims . . .." (quotation marks and citation omitted)); *Conoco, Inc. v. Energy & Environmental Int'l, L.C.*, 460 F.3d 1349, 1358 (Fed. Cir. 2006) (stating that "when a claim term is expressed in general descriptive words, we will not ordinarily limit the term to a numerical range that may appear in the written description or in other claims") (internal quotation omitted).

At the same time, however, a patentee may act as his or her own lexicographer – *i.e.*, specifically define his or her own terms. If the intrinsic evidence reveals a "special definition," then "the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316.

The prosecution history can further inform the meaning of claim terms by understanding how the inventors understood the claimed invention. *Id.* at 1317. However, given its potential ambiguity, the prosecution history is less important than other intrinsic evidence. *Id.*

Courts also may consider "extrinsic" evidence, such as expert testimony, dictionaries, and learned treatises, to ascertain how a skilled artisan would have understood claim terms. *See Phillips*, 415 F.3d at 1317; *Markman*, 52 F.3d at 980. Although extrinsic evidence carries less weight than intrinsic evidence, it may be useful "because extrinsic evidence can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean, it is permissible for the district court in its sound discretion to admit and use such evidence." *Phillips*, 415 F.3d at 1319.

B. Infringement

Infringement is an issue on which Abbott bears the burden of proof by a preponderance of the evidence. To prove infringement under 35 U.S.C. § 271(e)(2)(A), Abbott must prove that Watson filed "an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2)(A); *see also In re Omeprazole Patent Litigation*, 536 F.3d 1361, 1367 (Fed. Cir. 2008). "To prove direct infringement, the plaintiff must establish by a preponderance of the evidence that one or more claims of the patent read on the accused device literally or under the doctrine of equivalents." *Medtronic, Inc. v. Boston Scientific Corp.*, 2011 WL 1193381, at *8 (D. Del., Mar. 30, 2011) (citing *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 261 F.3d 1329, 1336 (Fed. Cir. 2001)). A party may also indirectly infringe a patent under 35 U.S.C. § 271(b) by inducing another party to make, use, offer to sell, or sell a patented invention in the United States. Inducement requires the alleged infringer knowingly to induce infringement and possess specific intent to encourage direct infringement by another. *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (*en banc* in relevant part). Where an alleged infringer includes instructions in its proposed drug label that

will cause some users to infringe asserted method claims, it meets the requisite specific intent for induced infringement. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010). Abbott will seek to prove at trial infringement of the asserted claims by Watson's accused products or by the use of those products in accordance with Watson's proposed product labels, either literally or under the doctrine of equivalents. "To establish literal infringement, 'every limitation set forth in a claim must be found in an accused product, exactly.'" *Medtronic*, 2011 WL 1193381 at *8 (quoting *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995)).

A product infringes an asserted patent claim under the doctrine of equivalents if it includes parts or steps that are identical or equivalent to the requirements of the claim. *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 38-40 (1997). An accused product is equivalent to a requirement of an asserted claim if the differences between them are insubstantial. *See Graver Tank & Mfg. Co. v. Linde Air Prods. Co*., 339 U.S. 605, 607 (1950) (the doctrine of equivalents prevents an infringer from making "unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law."); *TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.3d 1364, 1377 (Fed. Cir. 2008) ("Infringement under the doctrine of equivalents may be found when the accused device contains an insubstantial change from the claimed invention.") (internal quotation marks omitted). One way to determine equivalency is to look at whether or not the accused product performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claimed invention. *See, e.g., TIP Sys.*, 529 F.3d at 1376; *Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1379 (Fed. Cir. 2006); *see also Graver Tank*, 339 U.S. at 608.

Equivalency is determined by what was known at the time of the activities accused of infringement, and not by what was known at the time the patent application was filed or when the patent issued. *Warner-Jenkinson*, 520 U.S. at 37.

Abbott has the burden to prove by a preponderance of the evidence that every limitation of the asserted claims of the patents-in-suit reads on Watson's proposed extended-release niacin products or the use of Watson's products, either literally or under the doctrine of equivalents.

C. Invalidity

Invalidity is an issue on which Watson bears the burden of proof by clear and convincing evidence. *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1353 (Fed. Cir. 2003); 35 U.S.C. § 282. An issued patent is presumed valid and the presumption of validity "exists at every stage of the litigation." *Canon Computer Sys., Inc. v. Nu-Kate Int'l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1998). Given this presumption, an alleged infringer "has the ultimate burden of persuasion to prove invalidity by clear and convincing evidence, as well as the initial burden of going forward with evidence to support its invalidity allegation." *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009). Where the Patent and Trademark Office ("PTO") has considered particular evidence or arguments during patent prosecution, the alleged infringer bears "the added burden of overcoming the deference due to the PTO" to prevail on those issues at trial. *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1304 (Fed. Cir. 2008); *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1360 (Fed. Cir. 1984) ("When an attacker simply goes over the same ground travelled by the PTO, part of the *burden* is to show that the PTO was wrong in its decision to grant the patent." (emphasis in original)). A party may challenge the validity of a patent, for example, on the grounds of anticipation, obviousness, or indefiniteness.

Only if Watson meets its burden of establishing a *prima facie* case of anticipation or obviousness will Abbott have a burden of production of evidence to rebut the *prima facie* case in support of non-anticipation or non-obviousness of the patent. *Id.* at 1376-77. If Watson is unable to meet its burden of first proving a *prima facie* case of anticipation or obviousness, Abbott would have no need to present rebuttal evidence of validity. Even if Watson were to establish a *prima facie* case of anticipation or obviousness, and regardless of what rebuttal evidence Abbott presents, the burden of proof of invalidity is unshifting and remains with Watson at all times. *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1580 (Fed. Cir. 1991) (noting that the burden of proof of invalidity is "heavy and unshifting").

1. Anticipation under 35 U.S.C. § 102

A party seeking to invalidate a patent claim by anticipation must show by clear and convincing evidence that a single allegedly invalidating prior art reference contains each and every element, either expressly or inherently, of the claimed invention. *Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 89, 994-95 (Fed. Cir. 2000). If a single element from a claim is not shown in the reference, then it does not anticipate. *Structrual Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984).

A prior art reference may anticipate without expressly disclosing a feature of the claimed invention only if "that missing characteristic is necessarily present, or inherent, in the single anticipating reference." *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003); *see also King Pharms., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1274 (Fed. Cir. 2010) ("[A]nticipation by inherent disclosure is appropriate only when the reference discloses prior art that must ***necessarily*** include the unstated limitation." (quoting *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1373 (Fed. Cir. 2002)) (emphasis and alteration in original)). Where

the claimed invention would not necessarily result from practicing the prior art, the prior art does not inherently anticipate. *See, e.g., Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047-48 (Fed. Cir. 1995); *see also Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1348-49 (Fed. Cir. 2004); *Albany Molecular Research, Inc. v. Dr. Reddy's Labs., Ltd.*, No. 09-4638, 2010 WL 2516465, at *5 (D.N.J. June 14, 2010) ("'The mere fact that a certain thing may result from a given set of circumstances is not sufficient' to establish inherency." (quoting *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981))).

Inherent anticipation—like express anticipation—requires that the reference be enabling. That is, the reference must disclose enough information such that a person of ordinary skill in the art could practice the invention without undue experimentation. *Schering*, 339 F.3d at 1381; *see also Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1346 (Fed. Cir. 2008).

A prior art reference does not anticipate if it does not enable a person of ordinary skill in the art to carry out the invention without undue experimentation. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1306 (Fed. Cir. 2006). Factors the court considers when determining whether a disclosure would require undue experimentation include: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, and (4) the predictability or unpredictability of the art. *Elan Pharms., Inc. v. Mayo Found.*, 346 F.3d 1051, 1054-55 (Fed. Cir. 2003).

An earlier filed patent is not prior art to a later filed patent under 35 U.S.C. § 102(e) if the invention claimed in the later filed patent was conceived and reduced to practice prior to the filing date of the earlier filed patent, or conceived prior to the filing date of the earlier filed patent with diligence through reduction to practice. *See Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576-79 (Fed. Cir. 1996); *Power Integrations, Inc. v. Fairchild Semiconductor Intern.,*

Inc., 585 F. Supp. 2d 568, 574-576 (D. Del. 2008). An invention is reduced to practice if it has been demonstrated to be suitable for its intended purpose. *Mahurkar*, 79 F.3d at 1578.

It is well settled that when a prior art reference and a claim recite overlapping ranges, the prior art does not anticipate unless it describes with "specificity" the claimed range. *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006) (holding that a prior art range of 150°C and 350°C did not anticipate a claimed range of 330°C to 450°C, and that a prior art range of 0.001% to 1.0% did not anticipate a claimed range of 0.1% to 5.0%). Moreover, a generalized disclosure in the prior art does not anticipate if it does not provide guidance on how to make the claimed invention to achieve its beneficial properties. *Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1572 (Fed. Cir. 1992).

2. Obviousness under 35 U.S.C. § 103

A party seeking to challenge the validity of a patent claim based on obviousness must demonstrate by clear and convincing evidence that the invention described in the patent would have been obvious to a person of ordinary skill in the art at the time the invention was made. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359-60 (Fed. Cir. 2007). This determination turns on factual inquiries involving: (1) the scope and content of prior art, (2) differences between claims and prior art, (3) the level of ordinary skill in pertinent art, and (4) objective indicia of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 86 (1966); *Procter & Gamble Co. v. Teva Pharmas. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009). In determining what would have been obvious to one of ordinary skill in the art at the time of the invention, the use of hindsight is not permitted. *KSR Intern. Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007). In fact, the Federal Circuit has cautioned against "the distortion caused by hindsight bias" in an obviousness analysis. *Id.*

A patent challenger must identify with specificity the combination of prior art references that allegedly render the claimed invention obvious. *See, e.g., Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1361 (Fed. Cir. 2011); *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1355 (Fed. Cir. 2007). Thus, a vague notion that the prior art renders the claimed invention obvious is insufficient to meet the challenger's burden demonstrating obviousness with specific evidence.

When a patent challenger contends that a patent is obvious in light of a combination of prior art references, the challenger must show by clear and convincing evidence that a person of ordinary skill in the art would have had "reason to attempt to make the composition or device, or carry out the claimed process, and would have had a reasonable expectation of success in doing so." *PharmaStem Therapeutics, Inc. v. ViaCell Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007). When combining references to establish a *prima facie* case of obviousness, the alleged infringer must "'identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.'" *See TransOcean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1303 (Fed. Cir. 2010) (quoting *KSR*, 550 U.S. at 401). Thus, the initial test for obviousness in light of a combination of prior art references has two requirements: (1) a reason to carry out the claimed invention, and (2) a reasonable expectation of success.

"If a patent challenger makes a *prima facie* showing of obviousness, the owner may rebut that showing with 'unexpected results' demonstrating 'that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected.'" *Procter & Gamble*, 566 F.3d at 994 (quoting *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995)); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358,

1365 (Fed. Cir. 2008) ("As this court has repeatedly explained, this evidence [of unexpected results] is not just a cumulative or confirmatory part of the obviousness calculus but constitutes independent evidence of non-obviousness."). Secondary considerations of non-obviousness, such as the invention's satisfaction of a long-felt, unmet need, skepticism followed by acceptance, third-party praise for the invention, failure of others to achieve the invention, copying of the invention, licensing of the invention, and commercial success of the invention may also rebut a *prima facie* case of obviousness and are often the most probative evidence of non-obviousness. *Id.* at 998; *Graham*, 383 U.S. at 17-18; *Pressure Prods. Med. Supplies v. Greatbatch Ltd.*, 599 F.3d 1308, 1319 (Fed. Cir. 2010). In regard to the consideration of long-felt, unmet need, the need is properly measured at the time of the invention. *Id.* at 998; *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 884 (Fed. Cir. 1998).

3. Indefiniteness Under 35 U.S.C. § 112

A party seeking to invalidate a patent claim based on indefiniteness under 35 U.S.C. § 112 must prove by clear and convincing evidence that "a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant area." *Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008). Claims are indefinite "only where a person of ordinary skill in the art could not determine the bounds of the claims, *i.e.*, the claims were insolubly ambiguous" and "only if reasonable efforts at claim construction prove futile." *Id.* at 1249; *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001). "The test for indefiniteness does not depend on a potential infringer's ability to ascertain the nature of its own accused product to determine infringement, but instead on whether the claim delineates to a skilled artisan the bounds of the invention." *Star Scientific, Inc. v. R.J. Reynolds*

Tobacco Co., 537 F.3d 1357, 1373 (Fed. Cir. 2008) (internal quotation omitted). In particular, terms of degree are not indefinite, so long as a person of ordinary skill in the art could ascertain the bounds of the invention without undue experimentation. *E.g.*, *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1383-84 (Fed. Cir. 2003) ("'[E]ffective amount' is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite, provided that a person of ordinary skill in the art could determine the specific amounts without undue experimentation.").

4. Enablement Under 35 U.S.C. § 112

A party seeking to invalidate a patent for lack of enablement under 35 U.S.C. § 112 bears the burden of demonstrating by clear and convincing evidence "that ***one of ordinary skill in the art*** would be unable to make the claimed invention without undue experimentation." *Johns Hopkins Univ. v. CellPro Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998) (emphasis in original). Accordingly, the patent specification need not disclose what would already be known to a person of ordinary skill in the art at the time of the invention. *See Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1382 (Fed. Cir. 1999); *see also Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1254 (Fed. Cir. 2004) ("[A] patent disclosure need not enable information within the knowledge of an ordinarily skilled artisan. Thus, a patentee preferably omits from the disclosure any routine technology that is well known at the time of application."). Moreover, "the fact that ***some*** experimentation may be necessary to produce the invention does not render the [asserted patent] invalid for lack of enablement." *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1338 (Fed. Cir. 2006) (emphasis in original); *see also Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1143, 1155 (Fed. Cir. 2004) (rejecting enablement defense even where "trial and error [was] required to practice the claimed invention"). Rather, the challenger must demonstrate that the

experimentation required to practice the invention "would be unduly laborious or beyond the reach of one of ordinary skill in the art." *Koito Mfg.*, 381 F.3d at 1155.

5. Written Description Under 35 U.S.C. § 112

A party seeking to invalidate a patent for failure to satisfy the written description requirement must show by clear and convincing evidence that the patent's specification fails to describe the invention "in sufficient detail that one skilled in the art can clearly conclude that the inventor invented what is claimed." *Cordis Corp. v. Medtronic Ave, Inc.*, 339 F.3d 1352, 1364 (Fed. Cir. 2003); *see also Boston Scientific Scimed, Inc. v. Cordis Corp.*, 392 F. Supp. 2d 676, 683 (D. Del. 2005) ("A challenger must provide clear and convincing evidence that persons skilled in the art would not recognize in the disclosure a description of the claimed invention."). Like the enablement requirement, "the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

6. Best Mode Under 35 U.S.C. § 112

As an initial matter, a party seeking to invalidate a patent for failure to disclose the best mode of the invention must prove by clear and convincing evidence that "at the time the patent application was filed, the inventor possessed a best mode of practicing the claimed invention." *Green Edge Enters., LLC v. Rubber Mulch Etc., LLC*, 620 F.3d 1287, 1296 (Fed. Cir. 2010). If the inventor subjectively had a best mode for the invention at the time of filing, the party challenging the patent must also show that "the inventor 'concealed' the preferred mode from the public." *Id.*

No violation of the best mode requirement results if the inventor did not possess a best mode for the claimed invention at the time of filing. *Bruning v. Hirose*, 161 F.3d 681, 687 (Fed. Cir. 1998). Moreover, the inventor need not disclose a best mode if he develops it subsequent to filing the application. *Id.* When other evidence suggests that the inventor did not have a best mode at the time of filing, later commercialization of a particular embodiment does not demonstrate a violation of the best mode requirement. *See, e.g.*, *Tex. Instrs. Inc. v. U.S. Int'l Trade Comm'n*, 871 F.2d 1054 (Fed. Cir. 1989) ("The fact that Texas Instruments may have manufactured a DRAM containing a different or better form of boosting means is not pertinent to whether the specification disclosed 'the best mode contemplated by the inventor in carrying out his invention.'"); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 588 F. Supp. 1455, 1467 (N.D. Tex. 1983) ("[The inventor] had not decided on a single preferred formulation at the time the patent was filed . . . . Failure to cite the marketed version of the . . . product did not violate the best mode requirement.").

The best mode requirement relates only to the claimed invention. *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 381 F.3d 1371, 1379 (Fed. Cir. 2004) ("The obligation to disclose the best mode relates to the invention that is described and claimed."). "Subject matter that is not part of the invention that is claimed need not be included in the specification, and thus is not subject to the best mode requirement." *Id.*; *see also Randomex, Inc. v. Scopus Corp.*, 849 F.2d 585, 890 (Fed. Cir. 1988).

Congress recently abolished the failure to disclose the best mode of the invention as a defense to patent infringement in newly filed infringement suits. *See* Leahy-Smith America Invents Act, Pub. L. 112-29, 125 Stat. 284, 328 (2011).

7. Obviousness-Type Double Patenting

Obviousness-type double patenting is a judicially-created doctrine designed "to prevent an inventor from effectively extending the term of exclusivity by the subsequent patenting of variations that are not patentably distinct from the first-patented invention." *Applied Materials, Inc. v. Advanced Semiconductor Materials, Inc.*, 98 F.3d 1563, 1568 (1996); *see also Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 999 (Fed. Cir. 2009). The obviousness-type double patenting inquiry compares the claims of an earlier patent to the claims of the asserted patent without taking into account a motivation to combine references or secondary considerations of non-obviousness. *Procter & Gamble*, 566 F.3d at 999.

III. Issues Of Law That Remain To Be Litigated

Abbott's identification of the issues of law in this case is informed by the applicable legal standards recited above. Abbott's identification of the issues that remain to be litigated is also based on the pleadings and discovery to date and Abbott's current understanding of the corresponding arguments Watson is likely to make in attempting to establish a *prima facie* case of anticipation, obviousness, lack of written description, lack of enablement, indefiniteness, failure to disclose the best mode, and obviousness-type double patenting. To the extent that Watson intends or attempts to introduce different or additional legal arguments, Abbott reserves its rights to contest those legal arguments, and to present any and all rebuttal evidence in response to those arguments, and will not be bound by the summary of remaining legal issues presented herein.

Based on Abbott's current understanding of Watson's properly asserted defenses, Abbott believes that the following issues of law remain to be litigated:

1. The meaning of certain disputed claim terms in the patents-in-suit based upon the language of the claims themselves, the patents' specifications, prosecution histories, and extrinsic evidence concerning how a person of ordinary skill in the art would have understood these disputed claim terms at the time of the invention of the patents-in-suit;

2. Whether Abbott has demonstrated by a preponderance of the evidence that Watson's generic 500 mg/40 mg extended release niacin/simvastatin product infringes claims 1, 3, and 5 of the '715 patent; claims 9 and 11 of the '229 patent; claims 1 and 3 of the '691 patent under 35 U.S.C. § 271;

3. Whether Abbott has demonstrated by a preponderance of the evidence that Watson's generic 1000 mg/20 mg extended release niacin/simvastatin product, or its use in accordance with Watson's proposed labeling, infringes or would induce others to infringe claims 1, 3, 5, 6, and 8 of the '428 patent; claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the '930 patent; claims 1, 3, 5, 6, and 8 of the '848 patent; claims 9 and 11 of the '715 patent; claims 25 and 27 of the '229 patent; claims 13 and 15 of the '691 patent; claims 16, 18, 25, and 26 of the '967 patent; and claims 2-5, 11-13, and 21-30 of the '035 patent under 35 U.S.C. § 271;

4. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 5, 6, and 8 of the '428 patent are anticipated under 35 U.S.C. § 102 by the asserted prior art;

5. Whether Watson has met its burden of proving by clear and convincing evidence that claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the ’930 patent are anticipated under 35 U.S.C. § 102 by the asserted prior art;

6. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 5, 6, and 8 of the ’848 patent are anticipated under 35 U.S.C. § 102 by the asserted prior art;

7. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 5, 9, and 11 of the ’715 patent are anticipated under 35 U.S.C. § 102 by the asserted prior art;

8. Whether Watson has met its burden of proving by clear and convincing evidence that claims 9, 11, 25, and 27 of the ’229 patent are anticipated under 35 U.S.C. § 102 by the asserted prior art;

9. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 13, and 15 of the ’691 patent are anticipated under 35 U.S.C. § 102 by the asserted prior art;

10. Whether Watson has met its burden of proving by clear and convincing evidence that claims 16, 18, 25, and 26 of the ’967 patent are anticipated under 35 U.S.C. § 102 by the asserted prior art;

11. Whether Watson has met its burden of proving by clear and convincing evidence that claims 2-5 and 11-13 of the ’035 patent are anticipated under 35 U.S.C. § 102 by the asserted prior art;

12. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 5, 6, and 8 of the ’428 patent are obvious under 35 U.S.C. § 103 in view of the asserted prior art, either alone or in combination, including:

    a. Whether Watson has met its burden of proving a *prima facie* case of obviousness by demonstrating by clear and convincing evidence that a person of ordinary skill in the art at the time of the inventions would have had (1) a reasoned basis to attempt to carry out the claimed methods and (2) a reasonable expectation that the claimed methods would successfully fulfill their intended purposes; and

    b. Whether unexpected results and/or secondary indicia of non-obviousness of the inventions of the ’428 patent rebut any *prima facie* case of obviousness set forth by Watson, including a long-felt need, skepticism followed by acceptance, third-party praise, failure of others, copying, licensing, and commercial success;

13. Whether Watson has met its burden of proving by clear and convincing evidence that claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the ’930 patent are obvious under 35 U.S.C. § 103 in view of the asserted prior art, either alone or in combination, including:

    a. Whether Watson has met its burden of proving a *prima facie* case of obviousness by demonstrating by clear and convincing evidence that a person of ordinary skill in the art at the time of the inventions would have had (1) a reasoned basis to attempt to make the claimed compositions or carry out the claimed methods and (2) a reasonable expectation that the

claimed compositions or methods would successfully fulfill their intended purposes; and

b. Whether unexpected results and/or secondary indicia of non-obviousness of the inventions of the ’930 patent rebut any *prima facie* case of obviousness set forth by Watson, including a long-felt need, skepticism followed by acceptance, third-party praise, failure of others, copying, licensing, and commercial success;

14. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 5, 6, and 8 of the ’848 patent are obvious under 35 U.S.C. § 103 in view of the asserted prior art, either alone or in combination, including:

a. Whether Watson has met its burden of proving a *prima facie* case of obviousness by demonstrating by clear and convincing evidence that a person of ordinary skill in the art at the time of the inventions would have had (1) a reasoned basis to attempt to carry out the claimed methods and (2) a reasonable expectation that the claimed methods would successfully fulfill their intended purposes; and

b. Whether unexpected results and/or secondary indicia of non-obviousness of the inventions of the ’848 patent rebut any *prima facie* case of obviousness set forth by Watson, including a long-felt need, skepticism followed by acceptance, third-party praise, failure of others, copying, licensing, and commercial success;

15. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 5, 9, and 11 of the ’715 patent are obvious under 35 U.S.C. § 103 in view of the asserted prior art, either alone or in combination, including:

    a. Whether Watson has met its burden of proving a *prima facie* case of obviousness by demonstrating by clear and convincing evidence that a person of ordinary skill in the art at the time of the inventions would have had (1) a reasoned basis to attempt to make the claimed compositions and (2) a reasonable expectation that the claimed compositions would successfully fulfill their intended purposes; and

    b. Whether unexpected results and/or secondary indicia of non-obviousness of the inventions of the ’715 patent rebut any *prima facie* case of obviousness set forth by Watson, including a long-felt need, skepticism followed by acceptance, third-party praise, failure of others, copying, licensing, and commercial success;

16. Whether Watson has met its burden of proving by clear and convincing evidence that claims 9, 11, 25, and 27 of the ’229 patent are obvious under 35 U.S.C. § 103 in view of the asserted prior art, either alone or in combination, including:

    a. Whether Watson has met its burden of proving a *prima facie* case of obviousness by demonstrating by clear and convincing evidence that a person of ordinary skill in the art at the time of the inventions would have had (1) a reasoned basis to attempt to make the claimed compositions and (2) a reasonable expectation that the claimed compositions would successfully fulfill their intended purposes; and

b. Whether unexpected results and/or secondary indicia of non-obviousness of the inventions of the ’229 patent rebut any *prima facie* case of obviousness set forth by Watson, including a long-felt need, skepticism followed by acceptance, third-party praise, failure of others, copying, licensing, and commercial success;

17. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 13, and 15 of the ’691 patent are obvious under 35 U.S.C. § 103 in view of the asserted prior art, either alone or in combination;

a. Whether Watson has met its burden of proving a *prima facie* case of obviousness by demonstrating by clear and convincing evidence that a person of ordinary skill in the art at the time of the inventions would have had (1) a reasoned basis to attempt to make the claimed compositions and (2) a reasonable expectation that the claimed compositions would successfully fulfill their intended purposes; and

b. Whether unexpected results and/or secondary indicia of non-obviousness of the inventions of the ’691 patent rebut any *prima facie* case of obviousness set forth by Watson, including a long-felt need, skepticism followed by acceptance, third-party praise, failure of others, copying, licensing, and commercial success;

18. Whether Watson has met its burden of proving by clear and convincing evidence that claims 16, 18, 25, and 26 of the ’967 patent are obvious under 35 U.S.C. § 103 in view of the asserted prior art, either alone or in combination;

a. Whether Watson has met its burden of proving a *prima facie* case of obviousness by demonstrating by clear and convincing evidence that a person of ordinary skill in the art at the time of the inventions would have had (1) a reasoned basis to attempt to carry out the claimed methods and (2) a reasonable expectation that the claimed methods would successfully fulfill their intended purposes; and

b. Whether unexpected results and/or secondary indicia of non-obviousness of the inventions of the ’967 patent rebut any *prima facie* case of obviousness set forth by Watson, including a long-felt need, skepticism followed by acceptance, third-party praise, failure of others, copying, licensing, and commercial success;

19. Whether Watson has met its burden of proving by clear and convincing evidence that claims 2-5, 11-13, and 21-30 of the ’035 patent are obvious under 35 U.S.C. § 103 in view of the asserted prior art, either alone or in combination;

a. Whether Watson has met its burden of proving a *prima facie* case of obviousness by demonstrating by clear and convincing evidence that a person of ordinary skill in the art at the time of the inventions would have had (1) a reasoned basis to attempt to carry out the claimed methods and (2) a reasonable expectation that the claimed methods would successfully fulfill their intended purposes; and

b. Whether unexpected results and/or secondary indicia of non-obviousness of the inventions of the ’035 patent rebut any *prima facie* case of obviousness set forth by Watson, including a long-felt need, skepticism

followed by acceptance, third-party praise, failure of others, copying, licensing, and commercial success;

20. Whether Watson has met its burden of proving by clear and convincing evidence that claims 3 of the ’428 patent is indefinite under 35 U.S.C. § 112;

21. Whether Watson has met its burden of proving by clear and convincing evidence that claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the ’930 patent are indefinite under 35 U.S.C. § 112;

22. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 5, 6, and 8 of the ’848 patent are indefinite under 35 U.S.C. § 112;

23. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 5, 9, and 11 of the ’715 patent are indefinite under 35 U.S.C. § 112;

24. Whether Watson has met its burden of proving by clear and convincing evidence that claims 9, 11, 25, and 27 of the ’229 patent are indefinite under 35 U.S.C. § 112;

25. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 13, and 15 of the ’691 patent are indefinite under 35 U.S.C. § 112;

26. Whether Watson has met its burden of proving by clear and convincing evidence that claims 16, 18, 25, and 26 of the ’967 patent are indefinite under 35 U.S.C. § 112;

27. Whether Watson has met its burden of proving by clear and convincing evidence that claims 2-5, 11-13, 21, and 26-30 of the ’035 patent are indefinite under 35 U.S.C. § 112;

28. Whether Watson has met its burden of proving by clear and convincing evidence that claim 3 of the ’428 patent is not enabled under 35 U.S.C. § 112;

29. Whether Watson has met its burden of proving by clear and convincing evidence that claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the ’930 patent are not enabled under 35 U.S.C. § 112;

30. Whether Watson has met its burden of proving by clear and convincing evidence that claim 3 of the ’848 patent is not enabled under 35 U.S.C. § 112;

31. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 5, 9, and 11 of the ’715 patent are not enabled under 35 U.S.C. § 112;

32. Whether Watson has met its burden of proving by clear and convincing evidence that claims 9, 11, 25, and 27 of the ’229 patent are not enabled under 35 U.S.C. § 112;

33. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 13, and 15 of the ’691 patent are not enabled under 35 U.S.C. § 112;

34. Whether Watson has met its burden of proving by clear and convincing evidence that claims 16, 18, 25, and 26 of the ’967 patent are not enabled under 35 U.S.C. § 112;

35. Whether Watson has met its burden of proving by clear and convincing evidence that claims 2-5, 11-13, 21, and 26-30 of the ’035 patent are not enabled under 35 U.S.C. § 112;

36. Whether Watson has met its burden of proving by clear and convincing evidence that claim 3 of the ’428 patent is invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

37. Whether Watson has met its burden of proving by clear and convincing evidence that claims 18-21, 25, 27-29, 51, 115, 133-136, 140, and 142-144 of the ’930 patent are invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

38. Whether Watson has met its burden of proving by clear and convincing evidence that claim 3 of the ’848 patent is invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

39. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 5, 9, and 11 of the ’715 patent are invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

40. Whether Watson has met its burden of proving by clear and convincing evidence that claims 9, 11, 25, and 27 of the ’229 are invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

41. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 13, and 15 of the ’691 patent are invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

42. Whether Watson has met its burden of proving by clear and convincing evidence that claims 16, 18, 25, and 26 of the ’967 patent are invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

43. Whether Watson has met its burden of proving by clear and convincing evidence that claims 2-5, 11-13, 21, and 26-30 of the ’035 patent are invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112;

44. Whether Watson has met its burden of proving by clear and convincing evidence that claims 1, 3, 5, 6, and 8 of the ’428 patent are invalid for failure to disclose the best mode of the invention under 35 U.S.C. § 112;

45. Whether Watson has met its burden of proving by clear and convincing evidence that claims 2-5, 11-13, and 21-30 of the ’035 patent are invalid for obviousness-type double patenting in view of the ’930, ’848, ’715, ’229, ’967, and ’691 patents;

46. Whether Abbott is entitled under 35 U.S.C. § 271(e)(4)(B) to injunctive relief precluding Watson from engaging in the manufacture, use, sale, offering for sale, or importation within the United States of the proposed products of Watson’s ANDA No. 20-0601 before the expiration date of last patent in this lawsuit to expire that has been infringed and not declared invalid; and

47. Any evidentiary issues raised by the parties’ objections to the evidence.

EXHIBIT G

DEFENDANTS' STATEMENT OF ISSUES OF LAW REMAINING TO BE LITIGATED

Defendants submit their Statement of Issues of Law that remain to be litigated without waiving their prior positions. Defendants reserve the right to litigate legal issues raised by Plaintiffs even if not specifically set forth herein. To the extent that Defendants' statement of issues of fact set forth in Exhibit __ contain issues of law, those issues are incorporated herein by reference. Should the Court determine that any issue identified in this Exhibit as an issue of law is more appropriately considered an issue of fact, Defendants incorporate such issues by reference into its statement of issues of fact. Defendants also incorporate by reference any portion of Defendants' Brief Statement of Intended Proofs to the extent it raises additional legal issues.

The legal issues remaining to be litigated include:

1. Whether Teva's 1000 mg / 20 mg strength accused product infringes the asserted claims of the '428, '930, '848, '715, '229, '691, '967, and '035 patents.

2. Whether Teva's 750 mg / 20 mg strength accused product infringes the asserted claims of the '428, '930, '848, '715, '229, '691, '967, and '035 patents.

3. Whether Teva's 1000 mg / 40 mg strength accused product infringes the asserted claims of the '428, '930, '848, '715, '229, '691, '967, and '035 patents.

4. Whether Watson's 1000 mg / 20 mg strength accused product infringes the asserted claims of the '428, '930, '848, '715, '229, '691, '967, and '035 patents.

5. Whether Watson 500 mg / 40 mg strength product infringes the asserted claims of the '715, '229, and '691 patents.[1]

[1] Plaintiffs are no longer asserting that Watson's 500 mg / 40 mg strength product infringes the '428, '930, '848, '967 or '035 patents.

6. Whether claims 1, 3, and 5–9 of the ’428 patent are anticipated under 35 U.S.C. § 102.

7. Whether claims 1, 3, and 5–9 of the ’428 patent are obvious under 35 U.S.C. § 103.Whether claim 3 of the ’428 patent is indefinite under 35 U.S.C. § 112.

8. Whether claim 3 of the ’428 patent is invalid for lack of written description under 35 U.S.C. § 112.

9. Whether claim 3 of the ’428 patent is invalid for lack of enablement under 35 U.S.C. § 112.

10. Whether claims 1, 3, and 5–9 of the ’428 patent are invalid for failure to disclose the best mode under 35 U.S.C. § 112.

11. The priority date of the ’428 patent.

12. Whether claims 18–21, 24–29, 51, 115, 133–136, and 139–144 of the ’930 patent are anticipated under 35 U.S.C. § 102.

13. Whether claims 18–21, 24–30, 51, 115, 133–36, and 139–44 of the ’930 patent are obvious under 35 U.S.C. § 103.

14. Whether claims 18–21, 24–30, 51, 115, 133–36, and 139–44 of the ’930 patent are indefinite under 35 U.S.C. § 112.

15. Whether claims 18–21, 24–30, 51, 115, 133–36, and 139–44 of the ’930 patent are invalid for lack of written description under 35 U.S.C. § 112.

16. The priority date of the ’930 patent.

17. Whether claims 1, 3, and 5–9 of the ’848 patent are anticipated under 35 U.S.C. § 102.

18. Whether claims 1, 3, and 5–9 of the ’848 patent are obvious under 35 U.S.C. § 103.

19. Whether claim 3 of the ’848 patent is indefinite under 35 U.S.C. § 112

20. Whether claim 3 of the ’848 patent is invalid for lack of enablement under 35 U.S.C. § 112.

21. Whether claim 3 of the ’848 patent is invalid for lack of written description under 35 U.S.C. § 112.

22. The priority date of the ’848 patent.

23. Whether claims 1, 3, 5, 7, 9, and 11 of the ’715 patent are anticipated under 35 U.S.C. § 102.

24. Whether claims 1, 3, 5, 7, 9, and 11 of the ’715 patent are obvious under 35 U.S.C. § 103.

25. Whether claims 1, 3, 5, 7, 9, and 11 of the ’715 patent are indefinite under 35 U.S.C. § 112.

26. Whether claims 1, 3, 5, 7, 9, and 11 of the ’715 patent are invalid for lack of enablement under 35 U.S.C. § 112.

27. Whether claims 1, 3, 5, 7, 9, and 11 of the ’715 patent are invalid for lack of written description under 35 U.S.C. § 112.

28. The priority date of the ’715 patent.

29. Whether claims 9, 11, 15, 17, 19, and 27 of the ’229 patent are anticipated under 35 U.S.C. § 102.

30. Whether claims 9, 11, 15, 17, 19, and 27 of the ’229 patent are obvious under 35 U.S.C. § 103.

31. Whether claims 9, 11, 15, 17, 19, and 27 of the ’229 patent are indefinite under 35 U.S.C. § 112.

32. Whether claims 9, 11, 15, 17, 19, 25, and 27 of the ’229 patent are invalid for lack of enablement under 35 U.S.C. § 112.

33. Whether claims 9, 11, 15, and 27 of the ’229 patent are invalid for lack of written description under 35 U.S.C. § 112.

34. The priority date of the ’229 patent.

35. Whether claims 1, 3, 13, and 15 of the ’691 patent were obvious under 35 U.S.C. § 103.

36. Whether claims 1, 3, 13, and 15 of the ’691 patent are indefinite under 35 U.S.C. § 112.

37. Whether claims 1, 3, 13, and 15 of the ’691 patent are invalid for lack of enablement under 35 U.S.C. § 112.

38. Whether claims 1, 3, 13, and 15 of the ’691 patent are invalid for lack of written description under 35 U.S.C. § 112.

39. The priority date of the ’691 patent.

40. Whether claims 1, 3, 13, 14, 16, 18, 25, and 26 of the ’967 patent are obvious under 35 U.S.C. § 103.

41. Whether claims 1, 3, 13, 14, 16, 18, 25, and 26 of the ’967 patent are indefinite under 35 U.S.C. § 112.

42. Whether claims 1, 3, 13, 14, 16, 18, 25, and 26 of the ’967 patent are invalid for lack of enablement under 35 U.S.C. § 112.

43. Whether claims 1, 3, 13, 14, 16, 18, 25, and 26 of the ’967 patent are invalid for lack of written description under 35 U.S.C. § 112.

44. The priority date of the ’967 patent.

45. Whether claims 2–5 and 11–13 of the ’035 patent are anticipated under 35 U.S.C. § 102 by the NCEP report.

46. Whether claims 2–5, 11–13, and 21–30 of the ’035 patent are obvious under 35 U.S.C. § 103.

47. Whether claims 2–5, 11–13, and 21–30 of the ’035 patent are indefinite under 35 U.S.C. § 112.

48. Whether claims 2–5, 11–13, 21, and 26–30 of the ’035 patent are invalid for lack of enablement under 35 U.S.C. § 112.

49. Whether claims 2–5, 11–13, 21, and 26–30 of the ’035 patent are invalid for lack of written description under 35 U.S.C. § 112.

50. Whether claims 2–5, 11–13, and 21–30 of the ’035 patent are invalid for obviousness-type double patenting.

51. The priority date of the ’035 patent.

LEGAL STANDARDS FOR ISSUES OF LAW

I. Noninfringement

1. The determination of infringement is a two-step process. First, the claim must be properly construed to determine its scope and meaning. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995).

2. After the claim is interpreted, it must be compared to the accused device or process to determine whether the claim's scope encompasses the accused device or process. *North Am.Vaccine, Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 1574 (Fed. Cir. 1993).

3. Literal infringement is established only if the properly interpreted terms of the claim read on the accused device or process. *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1468 (Fed. Cir. 1993).

4. Plaintiffs have the burden of proving infringement by a preponderance of the evidence. *Seal-Flex, Inc. v. Athletic Track & Court Constr.*, 172 F.3d 836, 842 (Fed. Cir. 1999).

5. Because each element of a claim is material and essential, Plaintiffs must show the presence of each and every element in the accused device to establish literal infringement. *CharlesGreiner & Co. v. Mari-Med Mfg., Inc.*, 962 F.2d 1031, 1034 (Fed. Cir. 1992).

6. Dependent claims contain all of the limitations of the independent claim on which they depend. 35 U.S.C. § 112, para. 4. Thus, if an independent claim is not infringed, then each of the corresponding dependent claims cannot be infringed. *Becton Dickinson & Co. v. C.R. Bard, Inc.*, 922 F.2d 792, 798 (Fed. Cir. 1990).

7. To establish induced infringement, Plaintiffs must prove that

   a. Defendants knowingly induced a third party to infringe,

   b. Defendants possessed specific intent to encourage the third party to infringement, and

c. the third party actually infringed.

DSU Med. Corp. v. JMS Co., 471 F.3d 1293, 1305–05 (Fed. Cir. 2006). The mere knowledge of possible infringement by a third party does not amount to inducement. *Id.*

8. That an accused product is bioequivalent to a marketed pharmaceutical product allegedly covered by the patent or patents at issue is irrelevant to the issue of infringement. *See Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342, 1349 n.3 (Fed. Cir. 2008) ("FDA equivalence is irrelevant to patent law because it involves fundamentally different inquiries"); *Abbott Labs. v. Sandoz, Inc.*, 486 F. Supp. 2d 767, 776 (N.D. Ill. 2007) ("An admission of bioequivalence is not an admission of infringement . . . . If bioequivalency meant per se infringement, no alternative to a patented medicine could ever be offered to the public during the life of a patent.").

II. Invalidity

A. Standard of Proof

9. Defendants bear the burden of proving invalidity by clear and convincing evidence. *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1036 (Fed. Cir. 2001). When prior art or other evidence not considered in the PTO is used to establish invalidity "there is . . . no reason to defer to the PTO so far as its effect on validity is concerned." *Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984). "Indeed, prior art not before the PTO may so clearly invalidate a patent that the burden is fully sustained merely by proving its existence and applying the proper law . . . ." *Id.* at 1359–60. As the Supreme Court recognized, when prior art is not disclosed to the PTO, "the rationale underlying the presumption—that the PTO, in its expertise, has approved the claim—seems much diminished." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007). When "the PTO did not have all material facts before it, its considered judgment may lose significant force." *Microsoft Corp. v. i4i Ltd. P'ship*, 131 S.

Ct. 2238, 2251 (2011). "And, concomitantly, the challenger's burden to persuade the jury of its invalidity defense by clear and convincing evidence may be easier to sustain." *Id.*

B. Anticipation

10. Under 35 U.S.C. § 102(a), a claimed invention is anticipated when the invention known or used by others in this country or described in a printed publication in this or a foreign country before the claimed invention was invented.

11. Under 35 U.S.C. § 102(b), a claimed invention is anticipated when the invention was disclosed in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

12. Under 35 U.S.C. § 102(e), a claimed invention is anticipated when the inventions was described in a published patent applications in the United States before the claimed invention was invented or when the invention was described in a patent granted on an application for patent by another in the United Stated before the claimed invention was invented.

13. Anticipation is determined from the perspective of a person of ordinary skill in the field of the invention. *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1576 (Fed. Cir. 1991), *overruled in part on other grounds*, *Abbott Labs. v. Sandoz, Inc.* 566 F.3d 1282 (Fed. Cir. 2009); *In re Graves*, 69 F.3d 1147, 1152 (Fed. Cir. 1995).

14. A single prior art reference is invalidating if the reference discloses, either expressly or inherently, each and every element of the asserted claim. *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1375 (Fed. Cir. 2005); *Scripps Clinic*, 927 F.2d at 1576.

15. "[T]he question whether a claim limitation is inherent in a prior art reference is a factual issue on which evidence may be introduced . . . ." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (citing *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)). Such evidence is viewed through the lens of persons of ordinary skill in the art.

Continental Can Co., 948 F.2d at 1268. "[I]nherency operates to anticipate entire inventions as well as single limitations within an invention." *Matsushita Elec. Indus. Co. Ltd. v. Cinram Int'l, Inc.*, 299 F. Supp. 2d 348, 362 (D. Del. 2004) (quoting *Schering Corp. v. Geneva Pharms. Inc.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003)). "Recognition of the inherent limitation by a person of ordinary skill in the art before the critical date is not required to establish inherent anticipation." *Id.* Therefore, where a reference does not expressly disclose a claim element, the reference still anticipates where a person of ordinary skill in the art would understand the reference as disclosing that element, and such element was within the knowledge of that person. *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1347 (Fed. Cir. 2000).

16. Likewise, it is well settled that a prior art publication anticipates a claimed invention "if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531 (Fed. Cir. 1985). Indeed, as this Court has held:

> [A]nticipation may be established if a missing claim element is within the knowledge of one of ordinary skill in the art. This gap in the reference may be filled with recourse to extrinsic evidence. Such evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Thus, extrinsic evidence of the knowledge of one of ordinary skill in the art is relevant in situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges.

DiscoVision Assocs. v. Disc. Mfg., Inc., 25 F. Supp. 2d 301, 344 (D. Del. 1998) (citations and quotations omitted).

17. Proper extrinsic evidence to consider in conducting an anticipation analysis includes not only the knowledge of those persons of ordinary skill in the art, but also the

specification and prosecution history of the patent, as well as the prior art. *See Glaverbel SocieteAnonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1554 (Fed. Cir. 1995).

18. The Federal Circuit has explained "anticipation does not require actual performance of suggestions in a disclosure." *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 468 F.3d 1366, 1382 (Fed. Cir. 2006) (quoting *Novo Nordisk Pharm., Inc. v. Bio-Technology Gen. Corp.*, 424 F.3d 1347, 1355 (Fed. Cir. 2005)). The relevant inquiry is whether the prior art disclosure allows one of ordinary skill in the art to "reasonably understand and infer" that it discloses every element of the claim at issue. *In re Baxter Travenol Labs*, 952 F.2d 388, 390 (Fed. Cir. 1991).

19. The same holds true for method claims. As the Federal Circuit explained, "in the context of a claimed method for treating a disease, a prior art reference need not disclose 'proof of efficacy' to anticipate the claim." *Gleave*, 560 F.3d at 1335 (citing *Impax Labs., Inc. v. AventisPharms., Inc.*, 468 F.3d 1366, 1381 (Fed. Cir. 2006); *Rasmusson*, 413 F.3d at 1326). For this reason, one cannot patent an old method by simply confirming that the method works. *See Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001) (explaining that newly discovered results of known processes are not patentable because those results are inherent in the known processes).

C. Obviousness

20. A patent is invalid for obviousness if the differences between the subject matter sought to be patented and the prior art would have been obvious to a person having ordinary skill in the art at the time of the claimed invention. 35 U.S.C. § 103 (2006); *Graham v. John Deere Co.*, 383 U.S. 1, 15 (1966).

21. Obviousness *is a ques*tion of law based on underlying findings of fact. *McNeil-PPC, Inc. v. L. Perrigo Co.,* 337 F.3d 1362, 1368 (Fed. Cir. 2003). The underlying factual inquiries are:

a. the level of ordinary skill in the pertinent art at the time of the invention;

b. the scope and content of the prior art;

c. the differences, if any, between the claimed invention and the prior art; and

d. secondary considerations, if any, of non-obviousness.

Graham, 383 U.S. at 17–18; *McNeil-PPC*, 337 F.3d at 1368.

22. "[T]he results of ordinary innovation are not the subject of exclusive rights under the patent laws." *KSR*, 550 U.S. at 427.

1. Level of Ordinary Skill in the Art

23. Section 103 requires that a claim be declared invalid when the invention set forth in the claim is obvious to one of ordinary skill in the art to which the patent pertains. *In re GPAC, Inc.*, 57 F.3d 1573, 1579, 1583–84 (Fed. Cir. 1995). In determining the level of ordinary skill in the art, a court should consider the following factors: "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983). "Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case." *Id.* at 696–97. The hypothetical person of ordinary skill in the art is presumed to know all of the teachings of the prior art references in the field of the invention at the time the invention was made. *See Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1576 (Fed. Cir. 1984).

2. The Scope and Content of the Prior Art

24. In determining whether the claimed invention falls within the scope of the relevant prior art, a court first examines "the field of the inventor's endeavor" and "the particular problem with which the inventor was involved at the time the invention was made." *Monarch Knitting Mach.Corp. v. Sulzer Morat GmbH,* 139 F.3d 877, 881 (Fed. Cir. 1998) (citations and quotations omitted). Prior art references which are not within the field of the inventor's endeavor may still fall within the scope of the relevant prior art if the field of the reference is reasonably pertinent to the problem the inventor is trying to solve. *See, e.g.*, *GPAC*, 57 F.3d at 1577–78. Furthermore, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill." *KSR*, 550 U.S. at 401.

3. The Differences Between the Claimed Invention and the Prior Art

25. In ascertaining the differences between the claims at issue and the prior art, a court must consider both the claimed invention and the prior art as a whole in light of the court's construction of the claims at issue. *See Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1479–80 (Fed. Cir. 1998). A conclusion of obviousness may be made based on a single reference or a combination of prior art references if the references, taken as a whole, would have suggested the claimed invention to one of ordinary skill in the art. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986).

26. Obviousness is judged under "an expansive and flexible approach" driven by "common sense," and thus, patentability requires "more than the predictable use of prior art elements according to their established functions." *KSR*, 550 U.S. at 401–02. In *KSR*, the Supreme Court rejected the rigid application of the "teaching, suggestion and motivation" test

previously employed by the Federal Circuit, in favor of a more flexible obviousness standard. *Id.* at 419.

27. The Court held that the obviousness analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ," and it extends beyond just "published articles and the explicit content of issued patents." *Id.* at 418–19.

28. A claim to a method of using a compound for a particular function (i.e., treating a disease) is obvious when the prior art teaches the use of a structurally similar prior art compound to provide the same function. *See Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1259 (Fed. Cir. 2007). Likewise, a claim to a method of using a compound for a particular function (i.e., treating a disease) is obvious when the prior art discloses that compound and describes that compound's use for such function. *See, e.g.*, *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381, 1389 (Fed. Cir. 2010) (holding based on obviousness-type double patenting).

29. A patent claim can be proved obvious merely by showing that the combination of elements was obvious to try because, "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp." *KSR*, 550 U.S. at 402. A combination of prior art elements is obvious when "the prior art would have suggested to one of ordinary skill in the art that [the claimed invention] should be carried out and would have a reasonable likelihood of success." *Pfizer,* 480 F.3d at 1369; *see Pharmastem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007); *In re Dow Chem. Co.,* 837 F.2d 469, 473 (Fed. Cir. 1988); *see also Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1125 (Fed. Cir. 2000) (noting that "[t]he ultimate

determination of obviousness does not require absolute predictability of success"). "[O]nly a reasonable expectation of success, not a guarantee, is needed." *Pfizer*, 480 F.3d 1364 (citing *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988); *Brown & Williamson*, 229 F.3d at 1125).

4. Secondary Considerations of Nonobviousness

30. When a court reaches the conclusion that an asserted claim is *prima facie* obvious, the patentee may attempt to rebut that conclusion by presenting secondary considerations of nonobviousness. *WMS Gaming Inc. v. Int'l Game Tech.,* 184 F.3d 1339, 1359 (Fed. Cir. 1999).

31. Secondary considerations of nonobviousness may be considered "to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *Graham,* 383 U.S. at 17–18. But even when supported by substantial evidence, secondary considerations are often insufficient to overcome a *prima facie* case of obviousness. *KSR*, 550 U.S. at 427 ("Where, as here, the content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art are not in material dispute, and the obviousness of the claim is apparent in light of these factors, summary judgment is appropriate."); *see also Leapfrog Enters.*, 485 F.3d at 1162 (affirming this Court's finding of obviousness based on the strong *prima facie* obviousness showing despite "substantial evidence" of secondary considerations). Such evidence will not save a patent where there is "strong evidence of obviousness." *Brown &Williamson,* 229 F.3d at 1131. "The rationale for giving weight to the so-called 'secondary considerations' is that they provide objective evidence of how the patented device is viewed in the marketplace, by those directly interested in the product." *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 1391 (Fed. Cir. 1988) (citing *Graham,* 383 U.S. at 35–36).

32. Proffered secondary considerations may or may not be relevant to a determination of non-obviousness in a particular case. *Graham*, 383 U.S. at 18 ("As indicia of obviousness or

nonobviousness, these inquiries *may* have relevancy." (emphasis added)). "[T]he weight to be accorded evidence on secondary considerations is to be carefully appraised in relation to the facts of the actual case in which it is offered." *Cable Elec. Prods., Inc. v. Genmark, Inc.*, 770 F.2d 1015, 1026 (Fed. Cir. 1985), *overruled in part on other grounds*, *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999).

33. To establish secondary considerations of nonobviousness, mere " 'argument' and 'conjecture' are insufficient." *Demaco Corp.,* 851 F.2d at 1393 (citing *Rosemount, Inc. v. Beckman Instruments, Inc.,* 727 F.2d 1540, 1546 (Fed. Cir. 1984)). A patentee must establish a nexus between the evidence presented and the merits of the claimed invention, i.e., the patentee bears the burden of demonstrating "a legally and factually sufficient connection" between the evidence and the patented invention to demonstrate that the evidence offered does, in fact, corroborate the invention's nonobviousness. *In re Paulsen,* 30 F.3d 1475, 1482 (Fed. Cir. 1994); *see also GPAC*, 57 F.3d at 1580; *Ormco Corp. v. Align Tech., Inc.,* 463 F.3d 1299, 1311–12 (Fed. Cir. 2006) ("Evidence of commercial success, or other secondary considerations, is only significant if there is a nexus between the claimed invention and the commercial success.").

34. Secondary considerations "must be commensurate in scope with the claims which the evidence is offered to support." *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003).

35. Secondary considerations are legally irrelevant to the extent they relate only to unclaimed features of a commercial embodiment. *In re Vamco Mach. & Tool, Inc.*, 752 F.2d 1564, 1577 (Fed. Cir. 1985).

36. Secondary considerations do not control the obviousness determination. Even in situations where secondary considerations of nonobviousness and the required nexus is established, the evidence must be of sufficient weight to override a *prima facie* determination of

obviousness. *Ryko Mfg. Co. v. NuStar, Inc.,* 950 F.2d 714, 719 (Fed. Cir. 1991). Especially in light of *KSR*, courts have been reluctant to allow secondary factors to override a strong determination of obviousness based on primary considerations, even when all evidence relating to secondary factors is resolved in favor of the patentee. *See Apple Computer, Inc. v. Burst.com, Inc.*, No. C 06-0019, 2007 WL 3342829, at *5 n.1 (N.D. Cal. Nov. 8, 2007); *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 532 F. Supp. 2d 666 (D.N.J. 2007); *AdvanceMe Inc. v. RapidPay, LLC*, 509 F. Supp. 2d 593, 625 (E.D. Tex. 2007); *Asyst Techs., Inc. v. Empak, Inc.*, No. 98-20451, 2007 WL 2255220, at *8–9 (N.D. Cal. Aug. 3, 2007); *Friskit, Inc. v. RealNetworks, Inc.*, 499 F. Supp. 2d 1145, 1154 (N.D. Cal. 2007).

37. Even substantial secondary indicia of nonobviousness will not save an obvious invention. *See Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007) (finding that substantial evidence of secondary considerations did not overcome finding of obviousness); *Pfizer*, 480 F.3d at 1372 (holding that unexpectedly superior results did "not overcome the strong showing of obviousness in this case").

a. Unexpected Results

38. When a patentee attempts to rely on unexpected results of a claimed invention, the patentee must "show that the claimed invention exhibits some *superior property or advantage* that a person of ordinary skill in the art would have found surprising or unexpected" compared to the prior art. *Geisler*, 116 F.3d at 1469 (internal quotation marks omitted) (emphasis added); *see also Santarus, Inc. v. Par Pharm., Inc.*, 720 F. Supp. 2d 427, 457–58 (D. Del. 2010) ("[A] party must produce evidence demonstrating 'substantially improved' results that are unexpected in light of the prior art."). Hence, the allegedly unexpected property of the claimed invention must prove to be a *significant* benefit in comparison to the prior art. *In re Eli Lilly &Co.*, 902 F.2d 943, 948 (Fed. Cir. 1990) (finding applicant "has not shown unexpected superiority" by failure to

show "a significant aspect of his claimed invention is unexpected in light of the prior art."); *In re Nolan*, 553 F.2d 1261, 1267 (C.C.P.A. 1977) (finding the assertion of unexpected properties that were not shown to be of great significance to the claimed invention could not overcome evidence of obviousness).

39. In order to establish this secondary consideration, a party must produce evidence demonstrating "substantially improved" results that are unexpected in light of the prior art. *In re Soni,* 54 F.3d 746, 751 (Fed. Cir. 1995). "Mere argument or conclusory statements . . . does not suffice." *Geisler,* 116 F.3d at 1470 (citation omitted), nor do "bare statements without objective evidentiary support," *CFMT, Inc. v. YieldUp Int'l Corp.,* 349 F.3d 1333, 1342 (Fed. Cir. 2003). "It is well settled that unexpected results must be established by factual evidence." *In re DeBlauwe,* 736 F.2d 699, 705 (Fed. Cir. 1984).

40. The Federal Circuit has made it clear that, to demonstrate unexpected properties, the patentee must compare the claimed invention with the closest prior art, and not with more distant art. *See Kao Corp. v. Unilever U.S., Inc.*, 441 F.3d 963, 970 (Fed. Cir. 2006) (stating "when unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art" (quoting *In re BaxterTravenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991)); *see also Abbott Labs. v. Andrx Pharms.,Inc.*, 452 F.3d 1331, 1345 (Fed. Cir. 2006) (same); *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984) ("[A]n applicant relying on comparative tests to rebut a prima facie case of obviousness must compare his claimed invention to the closest prior art."); *In re Wright*, 569, F.2d 1124, 1128 (C.C.P.A. 1977) (appellant's evidence "did not rebut the evidence of obviousness because it failed to compare appellant's invention with what the board considered to be the 'nearest prior art' ").

41. When a patentee asserts a difference in properties between the claimed invention and the prior art, the difference must be in kind rather than merely degree. *Merck*, 800 F.2d at 1099. Even if a "modification results in great improvement and utility over the prior art, it may still not be patentable if the modification was within the capabilities of one skilled in the art, unless the claimed ranges 'produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art.' " *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322 (Fed. Cir. 2004) (quoting *In re Huang*, 100 F.3d 135, 139 (Fed. Cir. 1996)). To rebut a *prima facie* case of obviousness, the evidence must "show that the properties of the [products] differed in such an appreciable degree that the difference was really unexpected." *Merck*, 800 F.2d at 1099; *see also Abbott Labs.*, 452 F.3d at 1345 (holding that it was understood in the art that side effects were linked to drug concentration in the blood and therefore it would be obvious to one of skill in the art that an extended release formulation would reduce side effects); *Huang*, 100 F.3d at 139 (holding that it was understood in the art that shock absorbing qualities of polyurethane were derived from its compressible nature and it would be obvious that increasing thickness would increase shock absorption).

b. Commercial Success

42. A patentee offering evidence of "commercial success" to support its nonobviousness contention bears the burden of showing both that (i) there was, in fact, commercial success, and (ii) that any such success is attributable to the claimed invention rather than to other, unrelated factors such as advertising, aggressive marketing, pricing differentials, or unclaimed features of the product. *See Paulsen,* 30 F.3d at 1482; *see also In re DBC*, 545 F.3d 1373, 1384 (Fed. Cir. 2005).

43. "Commercial success" does not support the nonobviousness of the claimed invention if the commercial success is due to features known in the prior art. *Tokia Corp. v.*

Easton Enters., Inc., 632 F.3d 1358, 1369 (Fed. Cir. 2011); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006).

44. Whether a product is a commercial success must be determined in the context of such product's relevant market. *Santarus,* 720 F. Supp. at 453–54. The weight given to commercial success in an obviousness determination depends on both the extent of the commercial success and the strength of the nexus between the commercial success and the merits of the claimed invention. *See Ashland Oil, Inc.*, 776 F.2d 281, 306 (Fed. Cir. 1985) ("The objective evidence of secondary considerations may in any given case be entitled to more or less weight, depending on its nature and its relationship to the merits of the invention.").

45. Factors that may be relevant to a commercial success inquiry include the profitability of the product, displacement of other products in the marketplace, and whether the product has met internal performance goals. *See Cable Elec.*, 770 F.2d at 1026–27 (reversed on other grounds) ("Without further economic evidence . . . it would be improper to infer that the reported sales represent a substantial share of any definable market or whether the profitability per unit is anything out of the ordinary in the industry involved."); *Huang*, 100 F.3d at 140; *Kansas Jack, Inc. v. Kuhn*, 719 F.2d 1144, 1151 (Fed. Cir. 1983) ("There was no evidence of market share, of growth in market share, of replacing earlier units sold by others or of dollar amounts, and no evidence of nexus between sales and the merits of the invention."); *Emerson Elec. Co. v. SpartanTool, LLC*, 223 F. Supp. 2d 856, 914 (N.D. Ohio 2002) (considering evidence that original sales expectations were exceeded).

46. Even a strong showing of commercial success, without more, however, is insufficient by itself to counter strong evidence of obviousness. *See Richardson-Vicks Inc. v. Upjohn Co.,* 122 F.3d 1476, 1484 (Fed. Cir. 1997); *Newell Cos., v. Kenney Mfg. Co.,* 864 F.2d

757, 769 (Fed. Cir. 1988). Regardless of the strength of the evidence of commercial success, such success still must bear a nexus to the claimed features of the product. *See Sjolund*, 847 F.2d at 1582 ("Nor could the [fact-finder], from the bare evidence of units sold and gross receipts, draw the inference that the popularity of the [sold units] was due to the merits of the invention.").

47. When there is a first patent that would have prevented competitors from developing and selling the technology claimed in a second patent (i.e., a blocking patent) any asserted commercial success evidence is of very limited probative value to determining obviousness of the subsequent patent. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005); *see also Procter & Gamble Co. v. Teva Pharms. USA, Inc.,* 566 F.3d 989, 998 n.2 (Fed. Cir. 2009) (stating that a district court "rightly gave little weight" to commercial success where the prior art was itself the subject of a pending patent application); *Senju Pharm. Co. v. Apotex Inc. et al.*, Civ No. 07-779 (SLR), 2010 U.S. Dist. LEXIS 58338, at *54 (D. Del. June 14, 2010).

c. Long-Felt but Unsolved Need

48. A patentee may attempt to rely on evidence of a "long-felt *but unsolved need*" in the industry for the solution offered by a patented invention in attempting to overcome *a prima facie* finding that the invention is obvious. *Monarch Knitting,* 139 F.3d at 884. "[L]ong-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem." *Tex. Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993). In the context of drugs for use in human therapy, a "long-felt" need is not present where there are already other drugs of the same class in the marketplace. *See Aventis PharmaDeutschland GmbH v. Lupin, Ltd.,* 2006 WL 2008962, at *45 (E.D. Va. July 17, 2006) (finding that there "was simply no 'long felt need' " for a drug when "several effective" drugs of the same class were already on the market).

d. Skepticism and Praise

49. In order for a patentee to rely on skepticism and later praise as secondary considerations of nonobviousness, there must be skepticism directed to whether the claimed invention would work in general, not to whether the invention was better suited to solve the problem addressed than other inventions already in existence. *Ruiz v. A.B. Chance Co*., 357 F.3d 1270, 1274–75 (Fed. Cir. 2004). Furthermore, there must be skepticism by *skilled artisans* prior to the time of invention. *Santarus*, 720 F. Supp. 2d at 453; s*ee also In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988) (explaining that it is "[t]he skepticism of an expert, expressed before these inventors proved him wrong, [which] is entitled to fair evidentiary weight").

50. In order for a patentee to rely on any industry praise, the patentee must prove any such praise is attributable to material differences between the prior art and the patented invention as opposed to features held in common between the prior art and claimed invention. *Asyst Techs.,Inc. v. Emtrak, Inc.*, 544 F.3d 1310, 1316 (Fed. Cir. 2008).

e. Copying

51. A patentee in general may consider copying by others in the industry as a secondary consideration of nonobviousness. *Ecolochem, Inc. v. S. Cal. Edison Co.,* 227 F.3d 1361, 1380 (Fed. Cir. 2000). In generic drug litigation, evidence copying is of minimal—if any—relevance because copying "is what generic drug companies do." *Aventis Pharma Deutschland GmbH*, 2006 WL 2008962, at *45 (citing Moy's Walker on Patents 9:60 (4th ed. 2005)); *see also Aventis Pharma Deutschland GmbH. v. Lupin Ltd.*, 403 F. Supp. 2d 484, 486 (E.D. Va. 2005); *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, No. IP 02-0512-C-B/S, 2004 WL 1724632, at *38 n.21 (S.D. Ind. July 29, 2004). In the ANDA context, "given that there is a statute in place that encourages generic drug companies to challenge patents . . . [a] copying argument is weak." *Aventis Pharma Deutschland GmbH*, 2006 WL 2008962, at *45. As the

Court has said, an ANDA filing "is not persuasive objective evidence of non-obviousness." *Santarus*, 720 F. Supp. 2d at 458.

f. Failure of Others

52. The failure of others who have tried but failed to develop the claimed invention can be objective evidence of nonobviousness. *See, e.g.*, *KSR*, 550 U.S. at 406 (secondary factors are "utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented").

To establish the secondary consideration of failure of others, Plaintiffs bear the burden of producing evidence of "an articulated identified problem and *evidence of efforts* to solve that problem." *Tex. Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993) (emphasis added). Even if a plaintiff can meet its burden of proving that others have tried to solve the same problem but failed, the failure of others is probative only where the evidence shows that the prior failure occurred because "the devices lacked the claimed features.'" *Ormco,* 463 F.3d at 1313; *see also GPAC*, 57 F.3d at 1580 ("GPAC offers no evidence that this inability or unwillingness of competitors to respond to [the] invention in the marketplace is rooted in the subject matter claimed in the [patent]. Accordingly, this secondary consideration can be accorded only little weight as evidence of nonobviousness.").

D. Obviousness-Type Double Patenting

53. A basic premise of double patenting is that the same invention cannot be patented twice. *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1377 (Fed. Cir. 2003); *see also Perricone Corp.*, 432 F.3d 1368, 1372. Patent law restricts a person to only one patent per invention, 35 U.S.C. § 101; and also limits the terms of the patent monopoly on such invention, 35 U.S.C. § 154(A)(2). There are two recognized types of double-patenting: (1)

statutory double patenting; and (2) obviousness-type double patenting. *Perricone Corp.*, 432 F.3d at 1372.

54. Double patenting applies when the two patents at issue have at least one common inventor or are commonly assigned or owned. *Eli Lilly Co. v. Barr Labs., Inc*., 251 F.3d 955, 968 (Fed. Cir. 2001).

55. The judicially created doctrine of obviousness-type double patenting is designed to prevent a patentee from obtaining a second patent on substantially the same invention. *Geneva*, 349 F.3d at 1377–78. Obviousness-type double patenting prohibits obtaining a subsequent patent where the claims in the subsequent patent are not "patentably distinct" from the claims in the first patent. *Id*. A two-step test is employed to determine if obviousness-type double patenting exists. *See Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1326 (Fed. Cir. 1999). First, the court construes the claims in both the earlier and later patents and then overlays the later claim on the earlier claim to determine whether the later claim encompasses subject matter that was previously claimed. *Id*. The two claims are then analyzed to determine if they are patentably distinct. *Id*. at 1327. If the earlier claim anticipates the later claim or if the earlier claim renders the later claim obvious, the later claim is not patentably distinct and is invalid for obviousness-type double patenting. *Eli Lilly Co.,* 251 F.3d at 968 ("A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.").

56. In determining the distinctness of method claims, a later claimed use that is inherent or encompassed by the use of an earlier claim is not distinct. *Perricone*, 432 F.3d at 1375; *Eli Lilly*, 251 F.3d at 969. For example, the Federal Circuit recently made it clear that a claimed method of using a composition is not patentably distinct from an earlier claimed

composition where the earlier patent's specification disclosed the later-claimed use among other possible uses. *Sun Pharm.*, 611 F.3d at 1387. In carrying out the obviousness determination, prior art may be combined with the claims of the prior issued patent to establish obviousness-type double patenting. *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985).

57. Secondary considerations do not need to be considered when a defense is based on double patenting. *See Procter & Gamble*, 566 F.3d at 999; *Geneva Pharms., Inc. v.GlaxoSmithKline PLC*, 349 F.3d 1373, 1377 n.1 (Fed. Cir. 2003); *see also Astellas Pharma, Inc.v. Ranbaxy, Inc.*, No. 05-2563, 2007 WL 576341, at *4 (D.N.J. Feb. 21, 2007) (stating that "the proper inquiry for obviousness-type double patenting 'does not . . . involve an inquiry into objective criteria suggesting non-obviousness.'" (quoting *Applera Corp. v. MJ Research Inc.*, 363 F. Supp. 2d 261, 264 (D. Conn. 2005))); *Pfizer, Inc. v. Mylan Labs., Inc.*, No. 02:02CV1628, 2005 WL 2874997, at *3 (W.D. Pa. Nov. 2, 2005) (explaining that in an obviousness-type double patenting inquiry, "only the claims are to be compared, and the Court neither examines motivation to combine prior art references nor objective standards of non-obviousness" (citing *Geneva Pharms.*, 349 F.3d at 1378)).

E. Indefiniteness

58. Paragraph 2 of Section 112 requires that the claims of a patent "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention."

59. "Because claims delineate the patentee's right to exclude, the patent statute requires that the scope of the claims be sufficiently definite to inform the public of the bounds of the protected invention, i.e., what subject matter is covered by the exclusive rights of the patent. Otherwise, competitors cannot avoid infringement, defeating the public notice function of patent claims." *Haliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008).

60. Claims are indefinite where a claim "includes a numeric limitation without disclosing which of multiple methods of measuring that number should be used, *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1340 (Fed. Cir. 2003), [or when the claim] contains a term that is 'completely dependent on a person subjective opinion,' *Datamize LLC v. Plumtree Software, Inc*., 417 F.3d 1342, 1347 (Fed. Cir. 2005)." *Haliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008).

61. "Even if a claim terms definition can be reduced to words, the claim is still indefinite if a person of ordinary skill in the art cannot translate the definition into meaningfully precise claim scope." *Haliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008).

62. "A claim is considered indefinite if it does not reasonably apprise those skilled in the art of the its scope." *Microprocessor Enhancement Corp. v. Texas Instruments, Inc*., 520 F.3d 1367, 1374 (Fed. Cir. 2008) (quoting *IPXL Holdings, L.L.C. v. Amazon.com, Inc*., 430 F.3d 1377, 1383–84 (Fed. Cir. 2005)).

63. When a claim impermissibly mixes two or more classes of patentable subject matter, the claim is indefinite. *IPXL Holdings, L.L.C. v. Amazon.com, Inc*., 430 F.3d 1377, 1383–84 (Fed. Cir. 2005); *Aventis Pharma S.A. v. Hospira, Inc*., Case No. 08-496-GMS, slip op. at 21–22 (D. Del. Sept. 22, 2010) (holding composition claim invalid for reciting the method step "is used to form" or "form or is used").

F. Enablement

64. For purposes of patentability, the specification of a patent must contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to make and use it. 35 U.S.C. § 112, para. 1. To be enabling, the specification of a patent must teach those skilled in

the art how to make and use the full scope of the claimed invention without undue experimentation. *ALZA Corp. v. Andrx Parms., LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010). A court may consider the following factors when determining if a disclosure requires undue experimentation: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.*

65. The Federal Circuit has held that an enabled claim must "teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." *Id.* at 940. For instance, a claim that enables only one of two claimed embodiments is invalid for lack of enablement. *Id.* at 938–39.

G. Written Description

66. To meet the written description requirement of 35 U.S.C. § 112, the patent specification must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. *Ariad Pharms., Inc. v. Eli Lilly and Co*., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (citations omitted). "The specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed. *Id.*

67. The written description inquiry "is a question of fact. Thus, we have recognized that determining whether a patent complies with the written description requirement will necessarily vary depending on the context. Specifically, the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on

the complexity and predictability of the relevant technology. For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including 'the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue.' " *Ariad*, 598 F.3d at 1351.

68. As with enablement, the written description requirement is satisfied only if those "of ordinary skill in the art at the time the application was filed would recognize from the application that the inventor actually invented the full scope of the invention as finally claimed in the patent." *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1259 (Fed. Cir. 2004).

H. Best Mode

To meet the best mode requirement of 35 U.S.C. § 112, the patent specification must "set forth the best mode contemplated by the inventor of carrying out his invention." The best mode requirement has two parts. "The first is whether, at the time" the patent was filed, the inventor "knew of a mode of practicing [the] claimed invention that [the inventor] considered to be better than any other." *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 927–28 (Fed. Cir. 1990). Then, the "second part of the analysis compares what [the inventor] knew with what [the inventor] disclosed." *Id.* at 928. Specifically, this asks, in "largely an objective inquiry," if "the disclosure [is] adequate to enable one skilled in the art to practice the best mode or, in other words, has the inventor 'concealed' [the] preferred mode." *Id.*

EXHIBIT H

EXHIBIT H – ABBOTT'S LIST OF WITNESSES TO BE CALLED LIVE OR BY DEPOSITION

1. Plaintiffs Abbott Laboratories and Abbott Respiratory LLC (collectively, "Abbott") expect to call the witnesses identified below to testify at trial either live or by deposition.

2. Abbott reserves the right to call substitute witnesses to the extent that a witness becomes unavailable for trial. Abbott further reserves the right to call additional witnesses for impeachment purposes.

3. Abbott reserves the right to call at trial any witness who appears on Watson's witness list (*see* Exhibit I). If any of Watson's witnesses fail to appear at trial, Abbott reserves the right to use their deposition testimony.

4. The following is a list of witnesses whom Abbott expects to call live at trial:

Fact witnesses:

(a) David Bova

(b) Eugenio Cefali

Expert witnesses:

(a) Frank Sacks

(b) Michael Bottorff

(c) Robert Williams

(d) Daniel Smith

5. The following is a list of witnesses whom Abbott may call live at trial:

Fact witnesses:

(a) Marianne Sutcliffe

(b) Medgar Williams

(c) Robert Padley

6. The following is a list of witnesses whom Abbott may call at trial, either live or by deposition:

Fact witnesses:

(a) George Toth

(b) Mark McGovern

7. Abbott may call in rebuttal any of the witnesses listed above. Abbott further reserves the right to designate or counter-designate portions of deposition transcripts in rebuttal and/or to render complete any deposition designations made by Watson.

8. Abbott reserves the right to call any witness called by Watson, including seeking testimony beyond the scope of the direct testimony of Watson's witnesses who testify at trial.

EXHIBIT I

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

Abbott Laboratories and Abbott Respiratory LLC, Plaintiffs, v. Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd., Defendants.	)	
	)	Case No. 10-cv-00057-SLR-MPT (Consolidated)
Abbott Laboratories and Abbott Respiratory LLC, Plaintiffs, v. Watson Laboratories, Inc.–Florida, Defendant.	)	

Defendants' First Amended Witness List

Pursuant to Paragraph 10 of the Court's Scheduling Order dated July 29, 2010 (D.I. 29), Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd. and Watson Laboratories, Inc.–Florida (jointly, "Defendants") identify each fact witness they intend to call at trial. Defendants reserve the right to:

(1) call anyone appearing on Plaintiffs' witness list;

(2) call additional witnesses in rebuttal to those witnesses called by Plaintiffs;

(3) call additional witnesses to the extent necessary to provide foundational testimony if Plaintiffs contest the authenticity or admissibility of any materials to be offered at trial;

(4) call additional witnesses to respond to issues raised after the submission of this list, such as witnesses who have not yet been deposed;

(5) call any witness for purposes of impeachment;

(6) substitute witnesses on this list, should any of the listed witnesses become unavailable for trial;

(7) call any witness designated by Plaintiffs;

(8) call for live testimony any witness previously identified to provide testimony by deposition; and

(9) provide testimony by deposition for any witness previously identified to be called for live testimony.

Defendants intend to call the following fact witness to testify live:

1. Vickie O'Neill.

Defendants intend to call the following fact witnesses live, or by deposition if Abbott does not call them to testify live at trial:

1. David Bova;
2. Eugenio Cefali;
3. Mark McGovern;
4. Robert Padley;
5. Marianne Sutcliffe;
6. George Toth; and
7. Medgar Williams.

Defendants intend to call the following fact witnesses by deposition:

1. Daniel Bell;
2. Joseph Errigo;
3. Thomas Ferder;
4. Keith Greathouse;
5. Christopher Kiritsy;

6. David Kropp;

7. Kevin Lanigan; and

8. Kuldip Raj Malhotra.

Defendants intend to call the following expert witnesses to testify live:

1. Philip A. Beutel, Ph.D.;

2. William F. Elmquist, Ph.D.;

3. Joseph M. Keenan, M.D.;

4. Michael B. Maurin, R.Ph., Ph.D.; and

5. Stephen W. Schondelmeyer, Ph.D.

In addition to the reservations above, Defendants reserve the right to add or change its witnesses in response to changes made by Plaintiffs to their arguments, witness lists, or other positions. Defendants also reserve the right to modify the list of witnesses from whom they intend to offer testimony by deposition within four days of receiving notice from Abbott that it does not intend to call such witness to testify live at trial.

Dated: November 21, 2011

YOUNG CONAWAY STARGATT & TAYLOR

By: s/ Christopher J. Sorenson
John W. Shaw (#3362)
Karen E. Keller (#4489)
The Brandywine Building
1000 West Street, 17th Floor
P.O. Box 391
Wilmington , DE 19899-0391
(302) 571-6600
kkeller@ycst.com

and

PHILLIPS, GOLDMAN & SPENCE, P.A.

By: s/ James R. Hietala
John C. Phillips, Jr. (No. 110)
Megan C. Haney (No. 5016)
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgslaw.com

and

Christopher J. Sorenson (admitted pro hac vice)
MERCHANT & GOULD PC
3200 IDS Center
80 South Eighth Street
Minneapolis, MN 55402
(612) 332-5300

Shane A. Brunner (admitted pro hac vice)
MERCHANT & GOULD PC
10 East Doty Street
Suite 600
Madison, Wisconsin
(608) 280-6750
Counsel for Watson Laboratories, Inc.–Florida

Mark D. Schuman (admitted pro hac vice)
Jeffer Ali (admitted pro hac vice)
Thomas R. Johnson (admitted pro hac vice)
Todd S. Werner (admitted pro hac vice)
Sarah M. Stensland (admitted pro hac vice)
James R. Hietala (admitted pro hac vice)
Jennell Bilek (admitted pro hac vice)
CARLSON, CASPERS, VANDENBURGH & LINDQUIST PA
225 South Sixth Street, Suite 3200
Minneapolis, Minnesota 55402
612-436-9600
twerner@ccvl.com

Counsel for Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc.

EXHIBIT J

EXHIBIT J

Abbott's Deposition Designations, Watson's Counter Designations, and the Parties' Respective Objections

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
Boyer, Andrew	July 27, 2011	8:11-13			
		14:20-24			
		15:4-20			
		18:21-19:20			
		22:6-23:7			
		26:22-27:5			
		27:21-28:2			
		29:11-23			
		31:1-10			
		32:5-12			
		36:3-10	Foundation		
		36:12-18			
		36:21-37:6	Foundation		
		37:9-14			
		49:11-53:2			
		53:13	Incomplete		

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
		67:10-68:5		70:16-71:11	H, B
		72:4-10			
		72:12-25		73:3-18	H, B, K
		73:23-74:10		74:11-15	H
		81:15-23	Foundation	81:24-82:14 82:25-83:25	H, K (81:24-82:14), B (81:24-82:14) H
		96:7-17		96:18-97:3	H, K (96:21-97:3)
		104:23-105:1	Typographical error in question on line 24, "862,138,000" should be "$862,138"	104:23 105:13-22	NT (104:23), H (105:13-22); K (105:13-22) H
		110:6-9		110:10-15	H, S (110:15), NT (110:13-14)
		111:22-112:6			
		114:20-115:10	Foundation		
		115:13-116:8		128:18-130:10	H
		130:11-131:1			
Joshi, Mayank	June 30, 2011	5:5-7			
		25:16-18			

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
		27:24-28:3			
		46:7-14			
		46:24-50:14			
		54:7-15		87:9-88:7	H, LF, I, B, Improper Counter-Designation (87:14-88:7)
				109:14-110:17	H, LF, I, B, Improper Counter-Designation (110:14-17)
		112:2-113:3		113:4-119:12	H, LF, B, R, Improper Counter-Designation (114:12-115:11, 116:19-117:12; 117:22-118:3, 118:6-10)
				141:13-142:13	H, LF, Improper Counter-Designation (141:17-142:13)
				178:8-10	H, R, I, LF, K, Improper Counter-Designation

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
				189:11-21	H, LF, R, Improper Counter-Designation (189:18-21)
				196:20-25	H, LF, O, K, R
		197:1-8			
Manso, Peter	Dec. 12, 2003	4:17-19			
		10:22-11:6			
		11:21-12:11			
		35:7-13	H, R, C	35:24-25	I, R, NT
		35:18-23	H, R, C	35:2-9	
		151:22-152:6	H, R, C, P, I, O, E	152:12-14 152:16-24 153:20-21 154:2-3 155:19-21	S (155:19-21), L (155:19-21), LF (155:19-21), K (155:19-21), R (155:19-21)
		154:5-155:18	H, R, C, P, I, O, E	155:23-25 156:2-23	S (155:23-25), L, LF (155:23-25; 156:13-23), K (155:23-25), R (155:23-25), S (156:13-23)

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
McGovern, Mark	Aug. 27, 2003	5:14-16	H		
		70:24-71:4	H		
		71:11-17	H		
		143:10-144:9	C, E, F, H, P	25:12-19 172:11-13 177:14-16, 19-21, 23 178:24-179:5	LF (177:14-16, 19), O (177:14-16, 19)
		147:12-21	C, E, F, H, P	25:12-19 150:16-151:3	I (150:16-151:3)
		155:9-12	C, E, F, H, P	25:12-19	
		155:21-156:18	C, E, F, H, P, I	25:12-19	
		157:16-19	H	25:12-19	
		158:3-7	C, E, F, H, P	25:12-19	
		174:19-21	H	25:12-19 174:22-24 178:24-179:5	
		174:25	C, E, F, H, P	175:11-14	K
		175:3-10	C, E, F, H, P	175:11-14	K
		175:15-22	C, E, F, H, P	175:11-14	K
		186:25-187:16	C, E, F, H, P	25:12-19 188:2-10, 18	I (188:2-10, 18)
		188:19-21	C, E, F, H, P	25:12-19 188:2-10, 18	I (188:2-10, 18)
		189:5-10	C, E, F, H, P	25:12-19 188:2-10, 18 172:11-13	I (188:2-10, 18)
		189:18-24	C, E, F, H, P	25:12-19 188:2-10, 18 172:11-13	I (188:2-10, 18)

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
		190:5-10	C, E, F, H, P, I	25:12-19 188:2-10, 18 190:11-14 172:11-13	I (188:2-10, 18)
		190:18-191:4	C, E, F, H, P	25:12-19 188:2-10, 18 172:11-13	I (188:2-10, 18)
		192:7-193:13	C, E, F, H, P	25:12-19 188:2-10, 18 193:23-25 194:8-12 172:11-13	I (188:2-10, 18), B (193:23-25, 194:8-12)
		194:13-195:7	C, E, F, H, P	25:12-19 188:2-10, 18 195:8-18 172:11-13	I (188:2-10, 18), B (195:8-18)
		199:7-13	C, H, I	25:12-19	
		199:21-200:2	C, E, F, H, I, P	25:12-19 201:11-23	
		200:21-201:10	C, E, F, H, I, P	25:12-19 150:16-151:3 201:11-23 172:11-13	I (150:16-151:3)
		202:23-204:3	C, E, F, H, I, P	25:12-19 204:8-12 205:13-22 172:11-13	I (204:8-12), B (205:13-22)

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
		208:2-210:24	C, E, F, H, P	25:12-19 150:16-151:3 172:11-13 177:14-16, 19-21, 23 178:24-179:5 213:6-11 213:19-22 213:24 -214:7 214:10 -17 214:20 218:3-5 218:15-17 218:20-219:6 222:17-20	LF (177:14-16, 19; 214:4-7, 14-17), O (177:14-16, 19), Mischaracterizes Prior Testimony (214:4-7; 218:15-17); S (213:19-22; 214:14-17, 20) S (213:6-11, 218:3-5, 222:17-20)
		211:9-24	C, E, F, H, I, P	25:12-19 150:16-151:3 172:11-173:2 213:6-11 213:19-22 213:24 -214:7 214:10 -17 214:20 218:3-5 218:15-17 218:20-219:6 222:17-20	LF (177:14-16, 19; 214:4-7, 14-17), O (177:14-16, 19), Mischaracterizes Prior Testimony (214:4-7; 218:15-17); S (213:19-22; 214:14-17, 20) S (213:6-11, 218:3-5, 222:17-20)
		224:10-15	C, E, F, H, P	227:13-14 227:17-19 227:22	

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
		226:19-227:12	C, E, F, H, P	227:13-14 227:17-19 227:22	30(b)(6) (227:13-14; 227:17-19, 22), K (227:13-14; 227:17-19, 22), S (227:17-19, 22)
		242:12-17	C, E, F, H, P	25:12-19	
		242:22-244:9	C, E, F, H, P		
		244:22-23	C, E, F, H, P		
		244:25-245:4	C, E, F, H, P		
		245:10-21	C, E, F, H, P		
		245:24-246:4	C, E, F, H, P		
		246:8-19	C, E, F, H, P		
		253:17-23	C, E, F, H, I, P		
		254:2-16	C, E, F, H, I, P	254:17-20	R
		254:21-22	C, E, F, H, I, P	254:17-20	R
		255:3-4	C, E, F, H, I, P		

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
McGovern, Mark	Dec. 3, 2003	266:11-15	E, F, H	264:12-23	
		266:20-269:1	C, E, F, H, P	264:12-23 273:22-23 274:2-8 274:12-18 274:21-275:10	30(b)(6) (273:22-23; 274:2-8, 12-8; 274:21-275:10), LF (273:22-23, 274:8), K (273:22-23, 274:2-8), L (274:4-8, 12-18; 274:21-275:10); Mischaracterizes Prior Testimony (274:4-8, 12-18)
		269:17-23	C, E, F, H	264:12-23 269:3-16 273:22-23 274:2-8 274:12-18 274:21-275:10	30(b)(6) (273:22-23; 274:2-8, 12-8; 274:21-275:10), LF (273:22-23, 274:8), K (273:22-23, 274:2-8), L (274:4-8, 12-18; 274:21-22); Mischaracterizes Prior Testimony (274:4-8, 12-18)

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
		273:10-21	C, E, F, H, P	264:12-23 273:22-23 274:2-8 274:12-28 274:21-275:10	30(b)(6) (273:22-23; 274:2-8, 12-8; 274:21-275:10), LF (273:22-23, 274:8), K (273:22-23, 274:2-8), L (274:4-8, 12-18; 274:21-22); Mischaracterizes Prior Testimony (274:4-8, 12-18)
Vaughn, Janet	June 21, 2011	5:5-16			
		23:6-9			
		25:20-26:9			
		29:8-23			
		59:19-60:14			
		61:21-62:3			
		62:15-63:2			
		63:21-25			
		64:4-17			
		64:22-65:16			
		65:20-66:1			

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
		66:6-8	Foundation		
		89:23-90:20		66:9-15	NT (66:9-12), H, R
		90:25-91:2		89:7-22	H
		91:23-92:14			
Vaughn, Janet	June 21, 2011	114:10-15			
		115:7-116:10			
		117:9-118:13			
		118:25-119:3			
		119:6-8			
		119:10-120:1	Foundation		
		120:4-5			
		120:7-121:1			
		121:4-5	Foundation		
		121:7-14			
		121:21-22			
		121:24-122:11			
		122:23-123:2	Foundation	123:3-10	H, NT (123:7-8)
		123:21-124:1	Compound question		
		124:9-23	Foundation		

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
		125:1-3			
		128:2-129:8		127:14-25	H, NT (127:20-21)
		129:11	Foundation; outside scope of 30(b)(6)		
		129:21-130:7	Foundation; outside scope of 30(b)(6)		
		130:10		129:13-19	H, NT (129:17-18)
		131:16-25	Foundation		
		132:1-6	Foundation		
		132:12-18		130:12-18	H, NT (130:16)
		132:21-22		131:7-14	H, NT (131:11)
		134:6-9			
		134:11-13			
		134:15-17		132:7-11	NT (132:10-11)
		134:22-23	Foundation		
		134:25-135:2	Foundation		
		135:4-5		132:24-133:3	H
		136:25-137:14	Foundation; outside scope of 30(b)(6); calls for legal conclusion to the extent it relates to claims of patents-in-suit	133:18-25	NT (133:22-25)
		137:17-18		134:3-5	NT, R

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
		137:20-22	Foundation; outside scope of 30(b)(6); calls for legal conclusion to the extent it relates to claims of patents-in-suit		
		138:1-18			
		138:21-22	Foundation; calls for legal conclusion; outside scope of 30(b)(6)		
		139:4-6	Foundation; calls for legal conclusion; outside scope of 30(b)(6)		
		139:8-10	Foundation; calls for legal conclusion; outside scope of 30(b)(6)		
		139:12-140:13	Foundation; calls for legal conclusion; outside scope of 30(b)(6)		
		140:17-20		136:8-23	H, NT (136:11-14, 22)
		141:4-17	Foundation		
		141:20-22			
		141:24-142:3			
		142:5-6		137:23-25	H
		142:17-143:1	Foundation		
		144:1-15	Foundation		
		144:19			
		144:21-22			
		144:25-145:4	Foundation		

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
		145:6-8			
		145:10-11		140:21-141:2	H, NT (140:23)
		145:13-22	Foundation		
		146:4			
		146:7	Foundation		
		146:9-10	Foundation		
		146:13-14		142:8-16	H, NT (142:13)
		146:16-147:25			
		148:3-4	Outside scope of 30(b)(6); foundation		
		148:12-20	Outside scope of 30(b)(6); foundation		
		149:10-11	Outside scope of 30(b)(6); foundation		
		149:25-150:17			
		151:20-23	Outside scope of 30(b)(6); foundation		
		151:25-152:14			
		153:23-155:2			
		155:11	Foundation		
		155:13-156:1			
		157:6-158:7	Foundation; outside scope of 30(b)(6)		
		158:18-159:23			

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
		159:25-160:5	Foundation		
		160:13-161:18	Foundation		
		163:9-16			
		163:19-22	Foundation; outside scope of 30(b)(6)	148:21-149:9	NT (148:21-149:1, 5, 9)
		163:24-164:1			
		164:4-7			
		164:9-165:11	Foundation		
		167:14-15	Foundation		
		167:17-168:1			
		168:7-18			
		168:25-169:5			
		169:12-170:2			
		170:5-6	Foundation		
		170:8-17			
		170:23-171:19			
		172:3-18	Foundation		
		172:21-22			
		173:3-174:6	Foundation; asked and answered		
		174:9-11			

Witness	Date	Plaintiffs' Direct Designations	Defendants' Objections	Defendants' Counter-Designations	Plaintiffs' Objections
		174:24-175:2			
		176:7-22		167:10-15	NT (167:12-13)
		177:9-178:2			
		178:12-13			
		178:15-16			
		179:7-21			
		179:25-180:9			
		180:19-181:4			
		182:3-25			

Key Of Watson's Objections to Abbott's Designations

Key	Objection
A	The exhibit has not been properly authenticated under rules 901, 902, or 903.
B	This is not the best evidence of the document it purports to be.
C	This document's or testimony's probative value is substantially outweighed by a danger of confusion of issues, undue delay, waste of time, or presentation of needlessly cumulative evidence under Rule 403.
E	This testimony seeks to offer an expert opinion on topics beyond the scope for which the expert was qualified under Rule 702.
F	No foundation has been laid to admit this document either because as no sponsoring witness has testified about it, for example, under Rule 803 or because a sponsoring witness lacks personal knowledge under Rule 611.
H	This document or testimony contains or embodies an out-of-court statement. It is inadmissible as hearsay if offered to prove the truth of that statement unless the proponent can qualify it as nonhearsay or an exception to hearsay under Rule 801 et seq. To the extent that it is offered for another purpose, it is confusing and prejudicial.
I	One or more other documents or other testimony ought to, in fairness, be considered along with this document or testimony.
ID	This document is an improper demonstrative exhibit that is not evidence under Rules 901 through 903 and 1002.
NP	This document was not properly produced during discovery or was not timely identified by Abbott and therefore it should be excluded.
O	This testimony or line of questioning offers or seeks to elicit opinion testimony from a lay witness beyond that permitted in Rule 701.
OS	This testimony is beyond the parties' agreed-upon 30(b)(6) scope and is therefore improper.
P	This document's or testimony's probative value is substantially outweighed by a danger of unfair prejudice under Rule 403.
R	This document or testimony is not relevant any issue in this case under Rules 401 and 402.
RM	This document or testimony is not relevant unless offered as proof of issue that is relevant to this case.

S	This document is an improper summary under Rule 1006 and either summarizes material that can be conveniently examined in court or is an inaccurate, incomplete, or misleading summary.
V&A	This question is vague and ambiguous because it is either indefinite and uncertain or susceptible to multiple interpretations.

Key of Abbott's Objections to Watson's Counter-Designations

Abbreviation	Objection
B	Not Best Evidence (FRE 1002, 1003 and/or 1004)
C	Cumulative, Duplicative, Wasteful or Undue Delay (FRE 403)
H	Hearsay/Improper Use of Deposition (FRE 802 and/or FRCP 32)
K	Lack of Personal Knowledge/Incompetent (FRE 602)
L	Calls for Legal Conclusion
NR	Nonresponsive
LF	Lack of Foundation (FRE 103, 104 and/or 105)
O	Improper Lay or Expert Opinion (FRE 701-703)
R	Relevance (FRE 402)
S	Calls for Speculation
I	Incomplete (FRE 106)
NT	Not Testimony
30(b)(6)	Beyond the Scope of the Rule 30(b)(6) Deposition Topic

EXHIBIT K

EXHIBIT K

Watson's Deposition Designations, Abbott's Counter-Designations, Watson's Counter-Counter Designations, and the Parties' Respective Objections

Witness	Deposition Designations FROM	TO	Plaintiffs' Objections	Plaintiffs' Counter-Designations	DEF Obj to PLF Counters	DEF Counters to PLF Counters
Thomas Ferder October 28, 2003						
	7:13	8:3				
	19:3	19:5				
	19:7	19:9				
	19:11	25:12	B (24:18-20) LF; S (24:21-25:12	62:5; 65:3-25; 66:6-9; 66:18-67:8; 68:17-69:13; 69:24-70:8	I, NT, R R, NT R, OD R, OD R, OD R, OD	
	25:22	26:4	LF; S	62:8-19		
	26:13	26:15				
	26:21	30:5	B (29:5-24)			
	30:25	32:22				
	33:3	33:5				
	33:7	33:13				
	35:9	35:17	I (35:17)			
	36:10	36:13	LF			
	37:12	37:15	LF			
	38:10	38:13	LF			

Witness	Deposition Designations FROM	TO	Plaintiffs' Objections	Plaintiffs' Counter-Designations	DEF Obj to PLF Counters	DEF Counters to PLF Counters
	41:7	41:11	LF			
Christopher Kiritsy September 18, 2003						
	6:13	6:22		5:6-9		
	7:8	8:6				
	13:18	14:15				
	15:22	16:6				
	74:9	74:10				
	77:8	77:19				
	79:10	79:24				
	80:2	80:10				170:7-8; 170:11-15; 170:19-23; 171:2-3; 171:19-24
	249:18	250:6	I	249:12-15; 250; 7-17	R, LF, H R, LF, H	
	250:23	252:3		169:17-20; 169:23-170:6; 248:4-249:11	R, LF, L, K, H, O R, LF, L, K, H, O R, LF	
	252:23	253:6	LF (253:3-6)			
	253:9	253:24	LF			
	254:2	254:20		254:21-255:16	R, LF, K	

Witness	Deposition Designations FROM	TO	Plaintiffs' Objections	Plaintiffs' Counter-Designations	DEF Obj to PLF Counters	DEF Counters to PLF Counters
	255:17	256:3				
	256:16	257:9	LF			
	257:15	258:4	LF	257:10-14		
	258:7	258:12	LF, K, O	258:13-259:2		
	259:3	259:14	LF			
David Kropp October 30, 2003						
	5:15	6:4				
	7:15	7:19				
	7:24	8:12				
	8:23	9:14				
	10:11	10:20				
	15:6	15:7	I			
	15:9	15:14				
	15:16	16:13				
	16:17	16:24				
	17:19	19:15		19:16-18		
	19:19	20:8		20:9-16		
	20:17	21:24				
	22:19	24:19				
	25:11	25:24		25:8-9		
	26:2	26:8				
	26:12	26:20	LF (29:12-17)			
	26:22	27:15				

Witness	Deposition Designations FROM	TO	Plaintiffs' Objections	Plaintiffs' Counter-Designations	DEF Obj to PLF Counters	DEF Counters to PLF Counters
	27:25	29:6				
	29:17	31:5	B (29:17-30:4)	42:12-14; 42:19-20; 43:2-6	R, OD R, OD R, OD	
	32:1	32:10		31:6-18		
	32:17	34:25	B (33:2-10)	42:12-14; 42:19-20; 43:2-6		
	35:4	38:3	B (36:1-8; 37:1-10)	42:12-14; 42:19-20; 43:2-6		
	38:5	40:4	B (39:1-8)			
	43:22	44:5				
Joseph Errigo						
	8:10	8:16				
	11:8	11:10				
	11:23	12:3				
	13:20	14:3				
	18:17	18:19	I			
	19:2	19:4				
	20:8	20:21				
	21:7	21:10				
	23:1	23:5				
	23:17	24:2				
	24:4	24:14				
	24:22	25:9				

Witness	Deposition Designations FROM	TO	Plaintiffs' Objections	Plaintiffs' Counter-Designations	DEF Obj to PLF Counters	DEF Counters to PLF Counters
	25:17	25:24				
	26:8	26:15				
	26:19	26:21				
	27:8	27:21	B (27:15-17; 27:19-20); I (27:21)	104:15-105:14	R, OD	
	28:12	28:18				
	28:22	28:24	NT			
	32:19	32:25	Mischaracterizes prior testimony; LF; S	33:5-13	R	
	46:10	46:12				
	46:14	47:6				
	47:13	47:16				
	47:18	48:6	B (47:19-22)	104:2-8; 104:15-105:2	R, OD	
	58:15	59:2				
	59:9	59:12		59:3-6; 59:13-15; 59:17-21		
	64:11	65:14	B (65:7-10); I (65:14)	104:15-105:14	R, OD	
	65:24	66:3				
	66:10	66:23				
	67:3	67:9	B (67:3-6)	104:9-105:14	R, OD	
	67:11	67:11				
	67:14	67:16				
	67:18	68:3				
	68:19	68:24				
	69:1	69:7	B (69:4-7)	104:15-105:14	R, OD	

Witness	Deposition Designations FROM	TO	Plaintiffs' Objections	Plaintiffs' Counter-Designations	DEF Obj to PLF Counters	DEF Counters to PLF Counters
	69:25	70:3		69:13-24; 70:4-13	R	
	70:14	70:18				
	72:16	73:3				
	75:12	75:15	Mischaracterizes prior testimony; LF	73:4-14	I	
	83:22	83:25	Mischaracterizes prior testimony; LF	80:11-15; 80:19-24; 82:14-20; 106:13-18; 109:23-110:15		
	100:6	100:22				
	101:13	101:17				
Keith Greathouse						
	7:12	7:15		7:2-4	R, I, C	
	9:15	9:22				
	10:3	10:5				
	10:16	10:22		10:13-15	R, C	
	11:10	11:13				
	11:16	12:8		40:17-41:11		
	13:5	13:15	LF, K, B	12:21-13:2	R, C	
	15:21	16:6	LF, K, B	14:18-15:3	R, C	
	16:8	16:8	LF, K, B			
	17:4	17:8	LF, K, B			
	18:14	18:18	LF, K			
	18:21	18:22	LF, K			
	30:14	30:18	LF, K, B	29:7-16, 18-22	R, C	

Witness	Deposition Designations FROM	TO	Plaintiffs' Objections	Plaintiffs' Counter-Designations	DEF Obj to PLF Counters	DEF Counters to PLF Counters
	30:20	30:20	LF, K, B			
	30:22	31:4	LF			
Kevin Lanigan						
	4:16	4:18				
	5:19	5:21				
	7:15	7:17				
	12:11	13:3				
	14:10	14:22				
	16:6	16:10	I (16:6)			
	16:16	17:21				
	18:4	18:15				
	20:2	20:5				
	20:8	20:10	I			
	20:16	20:20				
	20:22	21:16				
	22:21	22:25				
	23:4	23:8				
	23:25	24:19				
	24:22	25:1				
	27:7	27:10				
	27:17	27:19	R	26:20-25	R, C, I	
	28:1	28:6				
	28:9	28:11				
	28:13	28:16	I (28:16)			

Witness	Deposition Designations FROM	TO	Plaintiffs' Objections	Plaintiffs' Counter-Designations	DEF Obj to PLF Counters	DEF Counters to PLF Counters
	28:23	29:1				
	29:5	29:23	B (29:19-23)			
	30:2	30:11	B			
	30:14	30:17	S			
	30:21	31:3	S			
	31:6	31:8	S			
	31:11	31:21				
	31:25	32:19		33:1-4; 33:10-14; 33:18-25; 34:3-4	R, O	
	37:5	39:20				
	39:25	40:2				
	40:8	40:13				
	41:19	43:18	B (42:5-43:5)			
	43:21	44:10				
	44:12	46:4				
	46:19	46:24				
	49:3	49:5				
	49:13	50:2				
	60:21	60:24				
	61:2	61:10				
	61:13	61:15		61:16-18; 61:21-22		
	65:17	67:2	I (65:17); B (66:6-9)	54:1-8; 54:10-13; 54:16; 57:7-12; 57:16; 58:2-4; 58:8-11; 58:15; 61:23-62:1; 62:21-23; 63:2	R	

Witness	Deposition Designations FROM	TO	Plaintiffs' Objections	Plaintiffs' Counter-Designations	DEF Obj to PLF Counters	DEF Counters to PLF Counters
	67:5	67:9				
Kuldip Malhotra October 29, 2003						
	4:8	4:9		4:2-5		
	5:12	5:25				
	6:8	6:19				
	6:24	7:16				
	13:6	13:9				
	13:17	14:4				
	16:10	16:18				
	17:2	18:13				
	18:24	19:9				
	31:15	31:19		31:20-23; 35:9-11; 35:20-23; 37:2-5	I	33:4-11, 33:12-13, 16-19
	32:5	32:13		32:17-21	I	33:4-11, 33:12-13, 16-19
	61:9	62:12	S, LF, K (61:21-62:12)			62:13-21
	74:19	74:23	S, LF, K			
	76:10	76:15		76:16-19		
	128:17	129:8		130:9-11, 14-22; 130:23-131:11; 132:9-12		
	133:13	134:14	LF, K, S			
	142:21	142:23	LF	143:19-21; 143:24-144:5; 144:7-9;	LF, K, O, S	

Witness	Deposition Designations FROM	TO	Plaintiffs' Objections	Plaintiffs' Counter-Designations	DEF Obj to PLF Counters	DEF Counters to PLF Counters
				147:6-23		
	143:2	143:9	LF, K			
	143:12	143:18				
	154:21	154:24				
	156:23	157:2	LF, K	156:15-22; 157:3-8	I	157:9-158:2
	157:9	158:2	LF, K			
	204:23	205:3	I, LF, B			

Key of Abbott's Objections to Watson's Designations

Abbreviation	Objection
B	Not Best Evidence (FRE 1002, 1003 and/or 1004)
C	Cumulative, Duplicative, Wasteful or Undue Delay (FRE 403)
H	Hearsay/Improper Use of Deposition (FRE 802 and/or FRCP 32)
K	Lack of Personal Knowledge/Incompetent (FRE 602)
L	Calls for Legal Conclusion
NR	Nonresponsive
LF	Lack of Foundation (FRE 103, 104 and/or 105)
O	Improper Lay or Expert Opinion (FRE 701-703)
R	Relevance (FRE 402)
S	Calls for Speculation
I	Incomplete (FRE 106)
NT	Not Testimony
30(b)(6)	Beyond the Scope of the Rule 30(b)(6) Deposition Topic

Key Of Watson's Objections to Abbott's Counter-Designations

Key	Objection
A	The exhibit has not been properly authenticated under rules 901, 902, or 903.
B	This is not the best evidence of the document it purports to be.
C	This document's or testimony's probative value is substantially outweighed by a danger of confusion of issues, undue delay, waste of time, or presentation of needlessly cumulative evidence under Rule 403.
E	This testimony seeks to offer an expert opinion on topics beyond the scope for which the expert was qualified under Rule 702.
F	No foundation has been laid to admit this document either because as no sponsoring witness has testified about it, for example, under Rule 803 or because a sponsoring witness lacks personal knowledge under Rule 611.
H	This document or testimony contains or embodies an out-of-court statement. It is inadmissible as hearsay if offered to prove the truth of that statement unless the proponent can qualify it as nonhearsay or an exception to hearsay under Rule 801 et seq. To the extent that it is offered for another purpose, it is confusing and prejudicial.
I	One or more other documents or other testimony ought to, in fairness, be considered along with this document or testimony.
ID	This document is an improper demonstrative exhibit that is not evidence under Rules 901 through 903 and 1002.
NP	This document was not properly produced during discovery or was not timely identified by Abbott and therefore it should be excluded.
O	This testimony or line of questioning offers or seeks to elicit opinion testimony from a lay witness beyond that permitted in Rule 701.
OS	This testimony is beyond the parties' agreed-upon 30(b)(6) scope and is therefore improper.

P	This document's or testimony's probative value is substantially outweighed by a danger of unfair prejudice under Rule 403.
R	This document or testimony is not relevant any issue in this case under Rules 401 and 402.
RM	This document or testimony is not relevant unless offered as proof of issue that is relevant to this case.
S	This document is an improper summary under Rule 1006 and either summarizes material that can be conveniently examined in court or is an inaccurate, incomplete, or misleading summary.
V&A	This question is vague and ambiguous because it is either indefinite and uncertain or susceptible to multiple interpretations.

EXHIBIT L

AO 187 (Rev. 07/87) Exhibit and Witness List

UNITED STATES DISTRICT COURT

_____ DISTRICT OF DELAWARE

EXHIBIT L								
JOINT EXHIBIT LIST								
PRESIDING JUDGE				PLAINTIFFS' ATTORNEY			DEFENDANTS' ATTORNEY	
TRIAL DATE(S)				COURT REPORTER			COURTROOM DEPUTY	
Abbott Laboratories, et al. v. Teva Pharmaceutical Industries, et al.							**Case Number: 10-57 (SLR)(MPT) Consolidated**	
PTX. NO	**DTX.NO**	**JTX NO.**	**DATE OFFERED**	**MARKED**	**ADMITTED**	**DESCRIPTION OF EXHIBITS**	**BATES NUMBER**	**OBJECTIONS**
PATENTS/FILE HISTORIES								
		JTX-1				U.S. Patent No. 6,080,428	TV0005540 - TV0005553	
		JTX-2				U.S. Patent No. 6,129,930	TV0009844 - TV0009861	
		JTX-3				U.S. Patent No. 7,011,848	TV0022336 - TV0022348	
		JTX-4				U.S. Patent No. 6,406,715	TV0013706 - TV0013731	
		JTX-5				U.S. Patent No. 6,818,229	TV0019817 - TV0019847	
		JTX-6				U.S. Patent No. 6,676,967	TV0014693 - TV0014722	
		JTX-7				U.S. Patent No. 6,746,691	TV0015184 - TV0015211	
		JTX-8				U.S. Patent No. 6,469,035	TV0014328 - TV0014350	
		JTX-9				File History for U.S. Patent No. 6,080,428	ABB_SIM 00895092 - ABB_SIM 00895618	
		JTX-10				File History for U.S. Patent No. 6,129,930	ABB_SIM 00896818 - ABB_SIM 00897620	
		JTX-11				File History for U.S. Patent No. 7,011,848	ABB_SIM 00898223 - ABB_SIM 00898489	
		JTX-12				File History for U.S. Patent No. 6,406,715	ABB_SIM 00897621 - ABB_SIM 00898222	
		JTX-13				File History for U.S. Patent No. 6,818,229	ABB_SIM 00002488 - ABB_SIM 00002856	
		JTX-14				File History for U.S. Patent No. 6,676,967	ABB_SIM 00895619 - ABB_SIM 00896080	
		JTX-15				File History for U.S. Patent No. 6,746,691	ABB_SIM 00896081 - ABB_SIM 00896669	
		JTX-16				File History for U.S. Patent No. 6,469,035	TV0014351 - TV0014692	
		JTX-17				Declaration of David J. Bova Under 37 CFR § 1.131, submitted in 08/368,378, March 27, 1996	ABB_SIM 00000231 - ABB_SIM 00000234	
		JTX-18				File History for U.S. Serial No. 08/124,392	ABB_SIM 00884511 - ABB_SIM 00884580	
PUBLICATIONS								
		JTX-19				"Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults," Arch Intern Med., Vol. 148, No. 1, 1988		
		JTX-20				"Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II), Second Report of the Expert Panel on Detection Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II)."	ABB_SIM 00566005 - ABB_SIM 00566187	
		JTX-21				"Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III)," September 2002	ABB_SIM 00566188 - ABB_SIM 00566450	

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PTX. NO	DTX.NO	JTX NO.	DATE OFFERED	MARKED	ADMITTED	DESCRIPTION OF EXHIBITS	BATES NUMBER	OBJECTIONS
		JTX-22				Birjmohum, et al., "Increasing HDL cholesterol with extended-release nicotinic acid: from promise to practice," The Netherlands Journal of Medicine. 2004; 62(7/8):229-233	ABB_SIM 00566456 - ABB_SIM 00566460	
		JTX-23				Carlson, "Pronounced lowering of serum levels of lipoprotein Lp(a) in hyperlipidaemic subjects treated with nicotinic acid," Journal of Internal Medicine 1989: 226: 271-76	TV0145081 - TV0145087	
		JTX-24				Dalton et al., "Hepatotoxicity Associated With Sustained-Release Niacin," Am. J. Med. 93, 102-104 (1992)	ABB_SIM 01233743 - ABB_SIM 01233751	
		JTX-25				Elam et al., "Effects of Niacin on Lipid and Lipoprotein Levels and Glycemic control in Patients With Diabetes and Peripheral Arterial Disease," JAMA. 2000; 284:1263-1270.	ABB_SIM 00531306 - ABB_SIM 00531317	
		JTX-26				Etchason et al., "Niacin-Induced Hepatitis: A Potential Side Effect With Low-Dose Time-Release Niacin," Mayo Clin Proc 66, 23-28 (1991)	ABB_SIM 00883470 - ABB_SIM 00883475	
		JTX-27				Garg, et al., "Nicotinic Acid as Therapy for Dyslipidemia in Non-Insulin-Dependent Diabetes Mellitus," JAMA, August 5, 1990, Vol. 254, No. 6	ABB_S2_00106170 - ABB_S2_00106173	
		JTX-28				Gray et al., "Efficacy and Safety of Controlled-Release Niacin in Dyslipoproteinemic Veterans", Ann Intern Med. 1994;121:252-258	TV0044177 - TV0044184	
		JTX-29				Grundy, et al., "Efficacy, Safety, and Tolerability of Once-Daily Niacin for the Treatment of Dyslipidemia Associated With Type 2 Diabetes," Arch Intern Med. 2002;162:1568-1576	ABB_SIM 00566527 - ABB_SIM 00566535	
		JTX-30				Henkin, et al., "Rechallenge With Crystalline Niacin After Drug-Induced Hepatitis From Sustained-Release Niacin", JAMA, July 11, 1990, Vol. 264, No. 2	ABB_SIM 00566550 - ABB_SIM 00566552	
		JTX-31				Henkin, et al., "Niacin Revisited: Clinical Observations on an Important but Underutilized Drug," AM J MED Vol. 91, No. 102, 239-46 (1991)	ABB_SIM 00566553 - ABB_SIM 00566560	
		JTX-32				Kane, et al., Cholesterol and Glycemic Effects of Niaspan® in Patients with Type 2 Diabetes, Pharmacotherapy 2001;21(12):1473-1478	ABB_SIM 00566568 - ABB_SIM 00566573	
		JTX-33				Knopp et al., Equivalent Efficacy of a Time-Release Form of Niacin (Niaspan) Given Once-a-Night Versus Plain Niacin in the Management of Hyperlipidemia, Metabolism 1998 Sep;47(9):1097-1104	ABB_SIM 00566582 - ABB_SIM 00566589	
		JTX-34				Knopp, "Evaluating Niacin in its Various Forms," Am J Cardiol. 2000; 86(12A):51L-56L (2000)	ABB_SIM 00566590 - ABB_SIM 00566595	

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_____ DISTRICT OF DELAWARE

PTX. NO	DTX.NO	JTX NO.	DATE OFFERED	MARKED	ADMITTED	DESCRIPTION OF EXHIBITS	BATES NUMBER	OBJECTIONS
		JTX-35				Knopp, et al., "Contrasting Effects of Unmodified and Time-Release Forms of Niacin on Lipoproteins in Hyperlipidemic Subjects: Clues to Mechanism of Action of Niacin," Metabolism, Vol. 34, No. 7 (July 1985)	ABB_SIM 00539229 - ABB_SIM 00539237	
		JTX-36				Mullangi, et al., "Niacin and its metabolites: role of LC-MS/MS bioanalytical methods and update on clinical pharmacology. An overview," Biomed Chromatogr. (Jan. 2011), 218, 218-220.	ABB_SIM 01263130 - ABB_SIM 01263149	
		JTX-37				Mullin et al., "Fulminant Hepatic Failure After Ingestion of Sustained-Release Nicotinic Acid," Ann. Intern. Med., Vol. 111, 1989	ABB_S2_00154772 - ABB_S2_00154774	
		JTX-38				Piepho, The Pharmacokinetics and Pharmacodynamics of Agents Proven to Raise High-Density Lipoprotein Cholesterol, 86 THE AMERICAN JOURNAL OF CARDIOLOGY 35L, 40L .	ABB_SIM 01154524 – ABB_SIM01154529	
		JTX-39				Rader et al., "Hepatic Toxicity of Unmodified and Time-Release Preparations of Niacin," 92 Amer J Med. 1992;92:77-81	ABB_S2_00083263 - ABB_S200083267	
CORRESPONDENCE								
		JTX-40				Letter dated March 15, 1989 from D. Bova to E. Schaefer	ABB_S2_00044516	
		JTX-41				Memorandum of Meeting dated December 3, 1991 re: Meeting at sponsor's request to review preliminary trials and proposed clinical development program	ABB_SIM 00682106 - ABB_SIM 00682108	
		JTX-42				Memorandum dated October 14, 1994 from D. Bell to Dave, et al.	ABB_SIM 00529306 - ABB_SIM 00529310	
		JTX-43				Letter dated August 18, 1995 from D. Raineri to S. Trostle	ABB_SIM 00534652 - ABB_SIM 00534664	
		JTX-44				Memorandum dated September 13, 1995 from M. Myers, et al. to D. Bell, et al. re: Niaspan Stability Data	ABB_SIM 00682267 - ABB_SIM 00682270	
		JTX-45				Memorandum dated March 21, 1996 from E. Cefali to D. Bell, et al. re Hypotheses containing the relationship of niacin pharmacokinetics and clinical safety and efficacy	ABB_SIM 00552464 - ABB_SIM 00552470	
		JTX-46				Memorandum dated November 14, 1996 from C. Kiritsy to D. Bell re Indirect Comparison of Niaspan, Slo-Niacin, and Enduracin, Ex. 79; Kos Pharms. v. Barr Labs. (Case No. 02 CV 1683)	ABB_SIM 00528395	
		JTX-47				Memorandum dated March 21, 1997 from S. Jenkins to D. Bova re: Report from meeting with Dr. Peter Guengerich	ABB_SIM 00530902 - ABB_SIM 00530903	
		JTX-48				Memorandum dated April 7, 1997 from S. Jenkins to D. Bova re: Report from meeting with Dr. David Jollow	ABB_SIM 00530904 - ABB_SIM 00530905	

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PTX. NO	DTX.NO	JTX NO.	DATE OFFERED	MARKED	ADMITTED	DESCRIPTION OF EXHIBITS	BATES NUMBER	OBJECTIONS
		JTX-49				Memorandum dated May 30, 1997 from E. Cefali to J. Kalimtzis, et al., re Why is Niaspan a better product than the sustained-release niacin products on the market?	ABB_S2_00069736 - ABB_S2_00069737	
		JTX-50				Memorandum dated July 7, 1997 from S. Jenkins and E. Cefali to M. Blanford re: In Vitro - In Vivo Correlation of Niaspan Using F2 Criteria in Lieu of Bioequivalence Studies Following Minor Changes in Formulation or Changes in Manufacturing Site	ABB_SIM 00534632 - ABB_SIM 00534640	
		JTX-51				Memorandum dated July 14, 1997 from S. Jenkins and G. Cefali to M. Blanford re: F2 Criteria of the Production Lots	ABB_SIM 00551705 - ABB_SIM 00551708	
		JTX-52				Letter dated December 7, 1998 from D. Bova to Dr. Schaefer	ABB_S2_00192028 - ABB_S2_00192029	
		JTX-53				Letter dated May 26, 1999 from M. McGovern to A. Gotto	ABB_SIM 00684831	
		JTX-54				Letter dated May 27, 1999 from A. Gotto to M. McGovern	ABB_SIM 00684832	
		JTX-55				Facsimile dated November 20, 2007 from K. DiStefano to M. Fossler re: F2 Values and Rationale for Waiver of BE for Niaspan Site Change	ABB_SIM 00534718- ABB_SIM 00534731	
		JTX-56				Letter from M. Parks to D. Ross re NDA 22-078 Approval (Simcor)	ABB_S2_01960446 - ABB_S2_01960480	
		JTX-57				Letter dated January 19, 1989 from D. Bova to Dr. Schaefer	ABB_S2_00044517 - ABB_S2_00044518	
		JTX-58				Facsimile dated November 11, 1997 from Karen DiStefano regarding F2 Values and Rationale for Waiver of BE for Niaspan Site Change	ABB_SIM 00534718 - ABB_SIM 00534731	
NDA/CLINCIAL DOCUMENTS								
		JTX-59				A Pilot Efficacy Study of a Once-A-Day Sustained Release Niacin Formulation (Niaspan) In the Treatment of Primary Type IIa Hyperlipidemia, Protocol No. 91/02, January 31, 1991	ABB_SIM 00529701 - ABB_SIM 00529750	
		JTX-60				NIASPAN IND, March 9, 1990	ABB_SIM 00527732 - ABB_SIM 00527759	
		JTX-61				Study 89/04 A Single-Blind Placebo Controlled Pilot Study Comparing the Effect of Once-A-Day Versus Twice-a-Day Dosing of Niaspan on Serum Lipids, Final report, Kos Pharmaceuticals, Inc., August 1991	ABB_S2_00024983 - ABB_S2_00025573	
		JTX-62				NDA 20-381, Volume Number 2.41	ABB_S2_00043357 - ABB_S2_00043802	
		JTX-63				Investigation of the Effect of Sustained-Release Niacin on Serum Transaminases and Phosphorus, Protocol Number 94/07 Draft Report (July 6, 1995)	ABB_S2_00182024 - ABB_S2_00182095	

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_____ DISTRICT OF DELAWARE

PTX. NO	DTX.NO	JTX NO.	DATE OFFERED	MARKED	ADMITTED	DESCRIPTION OF EXHIBITS	BATES NUMBER	OBJECTIONS
		JTX-64				A Double-Blind Multi-Center Study of the Safety and Efficacy of Niaspan (Controlled-Release Niacin) Versus Gemfibrozil in Patients With Low Levels of High-Density Lipoprotein (HDL) Cholesterol, Protocol 96/05 Phase 4, Final Report, May 15, 2001	ABB_S2_00221432 - ABB_S2_00221626	
		JTX-65				Final Study Reports for Clinical Studies 96/08	ABB_SIM 00530912 - ABB_SIM 00530939	
		JTX-66				Clinical Study Report 91/18; NDA 20-381 Vol. 3.8	ABB_SIM 00004694 – ABB_SIM 00005044	
		JTX-67				Study 91/19, Kos Pharmaceuticals, NDA 20-381, Niaspan Controlled-Release Tablets, Human Pharmacokinetics and Bioavailability, Vol. 3.23	ABB_SIM 00009066 - ABB_SIM 00009400	
		JTX-68				Clinical Study Report 91/04; NDA 20-381, Volume 3.33	ABB_SIM 00011788 - ABB_SIM 00012142	
		JTX-69				Clinical Study Report 91/05; NDA 20-381, Volume 3.40	ABB_SIM 00014202 - ABB_SIM 00014349	
		JTX-70				Clinical Study Report 91/05; NDA 20-381, Volume 3.41	ABB_SIM 00014350 - ABB_SIM 00014695	
		JTX-71				Clinical Study Report 91/05; NDA 20-381, Volume 3.43	ABB_SIM 00015144 - ABB_SIM 00015417	
		JTX-72				NDA 20-381, Vol. 3.50, Summary Tables and Graphs for 91/15	ABB_SIM 00016860 - ABB_SIM 00017348	
		JTX-73				NDA 20-381, Vol. 3.51 Appendices for 91/15	ABB_SIM 00017349 - ABB_SIM 00017629	
		JTX-74				NDA 20-381, Vol. 3.52, Data Listings - Appendix G for 91/15 (0 Series - 5.0 Series)	ABB_SIM 00017630 - ABB_SIM 00018096	
		JTX-75				NDA 20-381, Vol. 3.56, Data Listings - Appendix G for 91/09 (11.0 Series - 14.0 Series)	ABB_SIM 00019161 - ABB_SIM 00019636	
		JTX-76				A Multi-Center, Open-Label Trial Of The Long-Term Safety And Efficacy Of Niaspan In Patients With Primary Hyperlipoproteinemia, Protocol Number 91/09	ABB_SIM 00020228 - ABB_SIM 00020287	
		JTX-77				Clinical Study Report 89/04; NDA 20-381, Volume 3.72	ABB_SIM 00024891 - ABB_SIM 00025286	
		JTX-78				Clinical Study Report 91/02; NDA 20-381, Volume 3.73	ABB_SIM 00025287 - ABB_SIM 00025705	
		JTX-79				NDA 20-381, Volume Listing for Report 91/04, A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan in Patients with Primary Hyperlipoproteinemia, Protocol No. 91/04 Final Report, Revised April 24, 1996	ABB_SIM 00026769 - ABB_SIM 00026935	
		JTX-80				Clinical Study Report 89/04; NDA 20-381Volume Number 2.14	ABB_SIM 00041948 - ABB_SIM 00042170	
		JTX-81				Clinical Study Report 91/02; NDA 20-381, Volume Number 2.16	ABB_SIM 00042548 - ABB_SIM 00042709	
		JTX-82				Clinical Study Report 91/04; NDA 20-381, Volume Number 2.23	ABB_SIM 00044757 - ABB_SIM 00045110	

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		JTX-83				Clinical Study Report 91/05; NDA 20-381, Volume Number 2.30	ABB_SIM 00046704 - ABB_SIM 00046985	
		JTX-84				Niacin ER/Simvastatin Tablets, Kos Life Sciences, Inc., 2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods, Table of Contents	ABB_SIM 00077051 - ABB_SIM 00077077	
		JTX-85				Clinical Study Report: 019-03-04-CP, November 14, 2006	ABB_SIM 00081555 - ABB_SIM 00081613	
		JTX-86				Kos Pharmaceutical, Inc., November 30, 1995, Protocol #91/19, Final Report Addendum	ABB_SIM 00255097 - ABB_SIM 00255529	
		JTX-87				Niacin extended-release/simvastatin, 2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods, R&D/09/652	ABB_SIM 00296265 - ABB_SIM 00296339	
		JTX-88				Letter dated March 26, 1990 from D. Bova to Food and Drug Administration	ABB_SIM 00526840 - ABB_SIM 00527171	
		JTX-89				Food and Drug Administration, Application to Market A New Drug for Human Use or an Antibiotic Drug for Human use, Niaspan Sustained-Release Tablets	ABB_SIM 00527187 - ABB_SIM 00527396	
		JTX-90				Department of Health and Human Services Application To Market A New Drug, Biologic, Or An Antibiotic Drug For Human Use	ABB_SIM 00527557 - ABB_SIM 00527561	
		JTX-91				A Three-Way Crossover Study of the Bioavailability of Niacin From a Sustained Release Formulation When Dosed in the Fed Versus Fasted States in Reference to an Immediate Release Formulation, Protocol No. 91/01, March 3, 1991	ABB_SIM 00529185 - ABB_SIM 00529250	
		JTX-92				Clinical Study Outline for Nicotinic Acid/Aspirin Study, Hyperlipidemic men and women	ABB_SIM 00529329 - ABB_SIM 00529336	
		JTX-93				A Three-Way Crossover Study of the Bioavailability of Niacin From a Sustained-Release Formulation When Dosed in the Fed Versus Fasted States in Reference To An Immediate-Release Formulation, Protocol No. 91/01, Final Report	ABB_SIM 00529364 - ABB_SIM 00529537	
		JTX-94				Final Study Report for Protocol 91/02, Vol. 1	ABB_SIM 00529538 - ABB_SIM 00529700	
		JTX-95				Final Report, Protocol 91/04, Rev. 1	ABB_SIM 00529751 - ABB_SIM 00529790	
		JTX-96				A Double-Blind Placebo Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan in Patients With Primary Hyperlipoproteinemia, Final Report, April 24, 1996	ABB_SIM 00529869 - ABB_SIM 00530027	
		JTX-97				A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan in Patents with Primary Hyperlipoproteinemia, Protocol Number 91/04, Final Report	ABB_SIM 00529869 - ABB_SIM 00530027	

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		JTX-98				Food and Drug Administration, Investigational New Drug Application (IND) for Niacin, March 26, 1990	ABB_SIM 00530041 - ABB_SIM 00530217	
		JTX-99				A Double-Blind Placebo-Controlled Multi-Center Trail of the Safety and Efficacy of Niaspan-A Dose-Escalation Study, Protocol Number 91/15, Final Report, Revised April 29, 1996	ABB_SIM 00530316 - ABB_SIM 00530468	
		JTX-100				The Pharmacokinetics of Niacin and its Three Major Metabolites Following Multiple-Dose Administration of Niaspan at 1000 mg, 1500mg, 2000mg and 3000 mg Doses, Protocol Number 94/10, Final Report, October 11, 1995	ABB_SIM 00530469 - ABB_SIM 00530774	
		JTX-101				Kos Niaspan Study 94/10 - Urine % Dose Recovered Analysis	ABB_SIM 00530875 - ABB_SIM 00530880	
		JTX-102				National Sales Meeting for Niaspan Delivery System, August 6, 1997	ABB_SIM 00530906 - ABB_SIM 00530911	
		JTX-103				Protocol 94/08 Final Report Abstract and Tables, October 19, 1995	ABB_SIM 00532842 - ABB_SIM 00532846	
		JTX-104				Protocol 94/09 Final Report Abstract and Tables, November 22, 1995	ABB_SIM 00532847 - ABB_SIM 00532855	
		JTX-105				Protocol 95/01 Final Report Abstract and Tables, November 7, 1995	ABB_SIM 00532856 - ABB_SIM 00532860	
		JTX-106				Invention Disclosure for "Hypotheses concerning possible niacin metabolites responsible for the toxicity observed with oral niacin formulations", April 18, 1996	ABB_SIM 00566755 - ABB_SIM 00566760	
LABELS								
		JTX-107				Niaspan Tablets Label		
		JTX-108				Zocor (simvastatin) Tablet Label		
		JTX-109				Advicor Label, October 20, 2010		
		JTX-110				Teva's Simcor Label, Version 2.0	TV0212076 - TV0212107	
		JTX-111				Lovastatin Package Insert, Dec. 19, 1991		
		JTX-112				Simvastatin Package Insert, April 19, 1995		
DEFENDANTS' DOCUMENTS								
		JTX-113				Watson ANDA No. 20-0601 Amendment (500/40 mg)	OCA000024 - OCA0003648	
		JTX-114				Watson ANDA No. 20-0601 (1000/20 mg)	WT0000001 - WT0016158	
		JTX-115				Watson ANDA No. 20-061 Amendment (Withdrawal of 500/20 mg and 750/20 mg dosage strengths)	WT0017165 - WT0017167	
		JTX-116				Withdrawn (Teva document)		
		JTX-117				Withdrawn (Teva document)		
		JTX-118				Withdrawn (Teva document)		
		JTX-119				Withdrawn (Teva document)		
		JTX-120				Watson's 1.14.1.3 Draft Labeling Tex for Niacin Extended-release and Simvastatin Tablets	OCA000146 - OCA000186	

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		JTX-121				Protocol 96/01 Final Report, "The Comparative Bioavailability of Two Sustained Release Niacin Products Relative to Niaspan," January 15, 1997	ABB_SIM00530785 - ABB_SIM00530825	
		JTX-122				Protocol 96/01 Final Report, "The Comparative Bioavailability of Two Sustained Release Niacin Products Relative to Niaspan," January 15, 1997	ABB_S2_00789385 - ABB_S2_00789460	
SALES/MARKETING/LICENSING								
		JTX-123				License Agreement dated February 7, 1997 between Upsher-Smith and Kos	ABB_S2_00149169 - ABB_S2_00149188	
		JTX-124				Distribution, Patent & Trademark License, Marketing and Supply Agreement dated October 23, 2002 between Kos and Merck	ABB_S2_00213119 - ABB_S2_00213188	
		JTX-125				Co-Promotion Agreement dated October 29, 2003 between Kos and Takeda	ABB_SIM 00531450 - ABB_SIM 00531490	
		JTX-126				Settlement and License Agreement dated April 12, 2005 between Kos and Barr	ABB_S2_01113798 - ABB_S2_01113820	
		JTX-127				Niaspan Annotated Sales Aid	ABB_S2_00246872 - ABB_S2_00246890	
		JTX-128				Think Higher, Think Niaspan	ABB_S2_00566646 - ABB_S2_00566650	
		JTX-129				Think Higher HDL-C, Think Niaspan	ABB_S2_00660641 - ABB_S2_00660648	
		JTX-130				Low HDL-C is Like an Accident Waiting to Happen	ABB_S2_00662817 - ABB_S2_00662824	
		JTX-131				Powerful Dual-Lipid Management	ABB_SIM 00577606 - ABB_SIM 00577623	
		JTX-132				In Simvastatin Patients Drive HDL-C Higher	ABB_SIM 00577642 - ABB_SIM 00577655	
		JTX-133				Simcor-Aggressive Targets Demand Comprehensive Lipid Management	ABB_SIM 00577656 - ABB_SIM 00577676	
		JTX-134				One Treatment, Two Targets… Simcor Powerful Dual-Lipid Management	ABB_SIM 00577705 - ABB_SIM 00577720	
		JTX-135				Simcor-Aggressive Targets Demand Comprehensive Lipid Management	ABB_SIM 00577721 - ABB_SIM 00577746	
		JTX-136				In Simvastatin Patients Drive HDL-C Higher	ABB_SIM 00579092 - ABB_SIM 00579112	
		JTX-137				Presentation "Dyslipidemia Q1 2008 Attitudes, Awareness, and Usage Report: Niaspan and Simcor, May 28, 2008, March Major AAU and April Awareness Tracker Results"	ABB_S2_00269771 - ABB_S2_00269988	
		JTX-138				Kos Pharmaceuticals, Inc. Advicor/Niaspan Awareness, Attitude, Usage, and Positioning Study, October 2003	ABB_SIM 00683448 - ABB_SIM 00683624	
		JTX-139				Kos Pharmaceuticals, Inc. Advicor/Niaspan Phase II Awareness, Attitude, and Usage Study, May 2004	ABB_SIM 00572395 - ABB_SIM 00572527	
		JTX-140				Presentation "2009 Niaspan Strategic Plan, Niaspan - Niacin Extended-Release Tablets"	ABB_S2_00948605 - ABB_S2_00948613	
		JTX-141				NIASPAN net sales, sales history, and TRx. (Exhibit 95 to 06/11/2010 Deposition of Marianne Sutcliffe)	ABB_SIM 00689224 - ABB_SIM 00689233	

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		JTX-142				Pharmaceutical Products Division, 2008 Plan -- Key Product P&L, Dyslipidemia Franchise $MM	ABB_SIM 00577568 - ABB_SIM 00577573	
		JTX-143				Proprietary Pharmaceuticals Division, US, 2011 Update Reference Package, Niaspan Dashboard Summary ($MM), Financial Sales Overview	ABB_SIM 00949882 - ABB_SIM 00949904	
		JTX-144				Niaspan 2007-2011 P&L	ABB_SIM 00949892 - ABB_SIM 00949897	
		JTX-145				Spreadsheet - Total Prescriptions, Source: IMS NPA	ABB_SIM 00949898 - ABB_SIM 00949904	
		JTX-146				IMS Summary Data - 2005 - 11/2010	ABB_SIM 01159779 - ABB_SIM 01159782	
		JTX-147				Kos Pharmaceuticals Form S-1 (December 17, 1996), available at http://sec.gov	ABB_SIM 00527797- ABB_SIM 00528167	
		JTX-148				Kos Pharmaceuticals Form 10-K (1997)		
		JTX-149				Kos Pharmaceuticals Form 10-K (1998)	ABB_SIM 00945245 - ABB_SIM 00945284	
		JTX-150				Kos Pharmaceuticals Form 10-K (1999)	ABB_SIM 00945285 - ABB_SIM 00945373	
		JTX-151				Kos Pharmaceuticals Form 10-K (2001)		
		JTX-152				Kos Pharmaceuticals Form 10-K (2004)	ABB_SIM 00938596 - ABB_SIM 00938725	
		JTX-153				Kos Pharmaceuticals Form 10-K (2005)		
		JTX-154				Abbott Laboratories Form 10-K (2006)	ABB_SIM 01217174 - ABB_SIM 01217287	
		JTX-155				Schondelmeyer Ex. 366, "Why Your Doctor Has Prescribed Niapan"	ABB_S2_02385790 - ABB_S2_02385797	
KOS DOCUMENTS								
		JTX-156				Kos Pharmaceuticals, Inc. Draft, November 20, 1997	ABB_SIM 00037509 - ABB_SIM 00037522	
		JTX-157				Timetable for Niaspan Development	ABB_SIM 00523468	
		JTX-158				Hollywood Production Lots 12 Summary	ABB_SIM 00534611 - ABB_SIM 00534613	
		JTX-159				Niaspan Tablets Clinical Lots / Production Lots	ABB_SIM 00534626 - ABB_SIM 00534631	
		JTX-160				Invention Disclosure for "A Controlled-Release Inpurt Which Manifests Selectd Characteristics of Immediate-Release and Sustained-Release Niacin", April 18, 1996	ABB_SIM 00566750 - ABB_SIM 00566754	

EXHIBIT M

EXHIBIT M

ABBOTT'S EXHIBIT LIST WITH DEFENDANTS' OBJECTIONS

Abbott hereby submits its exhibit list and Defendants' objections thereto. Defendants used the following abbreviations for objections to proposed exhibits:

A	The exhibit has not been properly authenticated under rules 901, 902, or 903.
BE	This is not the best evidence of the document it purports to be.
C	This document's or testimony's probative value is substantially outweighed by a danger of confusion of issues, undue delay, waste of time, or presentation of needlessly cumulative evidence under Rule 403.
E	This testimony seeks to offer an expert opinion on topics beyond the scope for which the expert was qualified under Rule 702.
F	No foundation has been laid to admit this document either because as no sponsoring witness has testified about it, for example, under Rule 803 or because a sponsoring witness lacks personal knowledge under Rule 611.
H	This document or testimony contains or embodies an out-of-court statement. It is inadmissible as hearsay if offered to prove the truth of that statement unless the proponent can qualify it as nonhearsay or an exception to hearsay under Rule 801 et seq. To the extent that it is offered for another purpose, it is confusing and prejudicial.
I	One or more other documents or other testimony ought to, in fairness, be considered along with this document or testimony.
ID	This document is an improper demonstrative exhibit that is not evidence under Rules 901 through 903 and 1002.
NP	This document was not properly produced during discovery or was not timely identified by Abbott and therefore it should be excluded.

O	This testimony or line of questioning offers or seeks to elicit opinion testimony from a lay witness beyond that permitted in Rule 701.
OS	This testimony is beyond the parties' agreed-upon 30(b)(6) scope and is therefore improper.
P	This document's or testimony's probative value is substantially outweighed by a danger of unfair prejudice under Rule 403.
R	This document or testimony is not relevant any issue in this case under Rules 401 and 402.
RM	This document or testimony is not relevant unless offered as proof of issue that is relevant to this case.
S	This document is an improper summary under Rule 1006 and either summarizes material that can be conveniently examined in court or is an inaccurate, incomplete, or misleading summary.
V&A	This question is vague and ambiguous because it is either indefinite and uncertain or susceptible to multiple interpretations.

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EXHIBIT M								
ABBOTT'S TRIAL EXHIBIT LIST								
PRESIDING JUDGE			PLAINTIFFS' ATTORNEY				DEFENDANTS' ATTORNEY	
TRIAL DATE(S)			COURT REPORTER				COURTROOM DEPUTY	
Abbott Laboratories, et al. v. Teva Pharmaceutical Industries, et al.							**Case Number: 10-57 (SLR)(MPT) Consolidated**	
PTX NO.	**DTX NO.**	**JTX NO.**	**DATE OFFERED**	**MARKED**	**ADMITTED**	**DESCRIPTION OF EXHIBITS**	**BATES NUMBER**	**OBJECTIONS**
PATENTS/FILE HISTORIES								
PTX-0017						Declaration of David Bova for U.S. Serial No. 08/368,378, August 17, 1995	ABB_SIM 00000198 - ABB_SIM 00000204	A, F, I, H, BE, C, P, R
PTX-0019						Declaration of David J. Bova Under 37 CFR § 1.131, submitted in 08/814,974, August 29, 1998	ABB_SIM 00000949 - ABB_SIM 00000954	A, F, I, H, BE, C, P, R
PTX-0020						Declaration of George M. Toth Under 37 CFR § 1.608(b), submitted in 08/363,378, February 26, 1999	ABB_SIM 00000434 - ABB_SIM 00000438	A, F, I, H, BE, C, P, R
PUBLICATIONS								
PTX-0025						Ahrens, "Dietary Fast and Coronary Heart Disease: Unfinished Business", The Lancet, December 22/29, 1979	ABB_SIM 01168801 - ABB_SIM 01168804	A, F, R, C, P, H, B
PTX-0026						Ahrens, “Dietary Fast and Coronary Heart Disease: Unfinished Business,” The Lancet, December 22/29, 1979	ABB_SIM 00898680 - ABB_SIM 00898683	A, F, R, C, P, H, B
PTX-0027						Alsheikh-Ali et al., “The Safety of Niacin in the U.S. Food and Drug Administration Adverse Event Reporting Database,” Am J Cardiol, 2008	ABB_S2_00262204 - ABB_S2_00262208	A, F, R, C, P, H, B
PTX-0028						American Diabetes Association, “American Diabetes Association Position Statement: Management of Dyslipidemia in Adults With Diabetes,” Diabetes Care Jan. 2002; 25(Supp. 1):S74-S77	ABB_SIM 00573087 - ABB_SIM 00573090	A, F, R, C, P, H, B
PTX-0029						American Diabetes Association, “Complications”	ABB_SIM 00695119 - ABB_SIM 00695121	A, F, R, C, P, H, B
PTX-0030						American Diabetes Association, American “Diabetes Association Position Statement: Dyslipidemia Management in Adults With Diabetes,” Diabetes Care Jan. 2004; 27(Supp. 1):S68-S71	ABB_SIM 00573091 - ABB_SIM 00573094	A, F, R, C, P, H, B
PTX-0031						American Heart Association, “Heart Disease & Stroke Statistics 2010"	ABB_SIM 01167679 - ABB_SIM 01167698	A, F, R, C, P, H, B
PTX-0032						Aronson, “Correction Factor for Dissolution Profile Calculations,” Journal of Pharmaceutical Sciences Vol. 82, No. 11 , (Nov. 1993)		A, F, R, C, P, H, B, I, NP

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PTX-0033						Ballantyne, et al., "Comparison of the efficacy and safety of a combination tablet of niacin extended-release and simvastatin with simvastatin 80 mg monotherapy: the SEACOAST II (high dose) study," Journal of Clinical Lipidology (2008) 2, 79-90	ABB_SIM 00270013 - ABB_SIM 00270024	A, F, R, C, P, H, B
PTX-0034						Ballantyne, et al., "Comparison of the Safety and Efficacy of a Combination Tablet of Niacin Extended Release and Simvastatin vs Simvastatin Monotherapy in Patients with Increased Non-HDL Cholesterol (from the SEACOAST I Study), 2008	ABB_SIM 00270025 - ABB_SIM 00270033	A, F, R, C, P, H, B
PTX-0035						Barboriak, et al., "Nicotinic Acid and Alcohol-Induced Lipemia," Atherosclerosis (1971)	ABB_SIM 01168998 - ABB_SIM 01169003	A, F, R, C, P, H, B
PTX-0036						Bays, "Safety of Niacin and Simvastatin Combination Therapy" (2008)	ABB_SIM 00270034 - ABB_SIM 00270039	A, F, R, C, P, H, B
PTX-0038						Blum, et al., "High density lipoprotein metabolism in man," J Clin Invest 60:795-807 (1977)	ABB_SIM 01182030 - ABB_SIM 01182042	A, F, R, C, P, H, B
PTX-0039						Budavari, Susan, "The Merck Index" (11th ed. 1989)	ABB_SIM 00535264 - ABB_SIM 00535266	A, F, R, C, P, H, B
PTX-0040						Buhler, Polyvinylpyrrolidone Excipients for Pharmaceuticals: Povidone, Crospovidone and Copovidone, p. 113 (2005)		A, F, R, C, P, H, NP
PTX-0041						Campbell, et al., "Consumers' Use of Persuasion Knowledge: The Effects of Accessibility and Cognitive Capacity on Perceptions of an Influence Agent," Journal of Consumer Research, 27: 69-83 (June 2000)	ABB_SIM 01197094 - ABB_SIM 01197109	A, F, R, C, P, H, B, I
PTX-0042						Canner, et al., "Fifteen Year Mortality in Coronary Drug Project Patients: Long-Term Benefit With Niacin," JACC, Vol. 8, No. 6, 1986	ABB_SIM 00684400 - ABB_SIM 00684410	A, F, R, C, P, H, B
PTX-0043						Capuzzi et al., "Efficacy and Safety of An Extended-Release Niacin (Niaspan): A Long-Term Study," Am J Cardiol. 1998; 82(12A):74U-81U	ABB_SIM 00566466 - ABB_SIM 00566473	A, F, R, C, P, H, B
PTX-0044						Carlson, "Niaspan, the prolonged release preparation of nicotinic acid (niacin), the broad-spectrum lipid drug," Int J Clin Pract. 2004; 58(7):706-713	ABB_SIM 00566474 - ABB_SIM 00566481	A, F, R, C, P, H, B, I

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PTX-0046						Carlson, et al., "Effect of a Single Dose of Nicotinic Acid on Plasma Lipids in Patients With Hyperlipoproteinemia," Acta Med. Scand. Vol. 183, pp. 457-462 (1968)	ABB_SIM 01169004 - ABB_SIM 01169013	A, F, R, C, P, H, NP
PTX-0047						Castelli, et al., "Incidence of coronary heart disease and lipoprotein cholesterol levels: The Framingham Study," JAMA 256(20):2835-8 (Nov. 1986)	ABB_S2_00200853 - ABB_S2_00200856	A, F, R, C, P, H, B
PTX-0048						Chen et al., "Niaspan Increases Angiogenesis and Improves Functional Recovery after Stroke," Annals of Neurology. 2007; 62(1):49-58	ABB_SIM 00566482 - ABB_SIM 00566491	A, F, R, C, P, H, B
PTX-0049						Chen et al., "Niaspan treatment increases tumor necrosis factor-α-converting enzyme and promotes arteriogenesis after stroke," Journal of Cerebral Blood Flow & Metabolism. 2009; 29:911-920	ABB_SIM 00566492 - ABB_SIM 00566501	A, F, R, C, P, H, B
PTX-0050						Cheung, et al., "Clinical utility of extended-release niacin: update and summary," Future Cardiol. 2005; 1(5):571-578	ABB_SIM 00566502 - ABB_SIM 00566509	A, F, R, C, P, H, B
PTX-0051						Cooper, Winning at New Products (3d ed. 2001)	ABB_SIM 00898830 - ABB_SIM 00898835	A, F, R, C, P, H
PTX-0052						Coppola, et al. "Niacin-Induced Hepatotoxicity: Unusual Presentations," Southern Medical Journal 1994; 87(1):30-32	ABB_SIM 00566870 - ABB_SIM 00566872	A, F, R, C, P, H, B
PTX-0053						Creavin, "Niaspan: new hope for heart patients," DDT. 2005; 10(1):4-5	ABB_SIM 00566510 - ABB_SIM 00566511	A, F, R, C, P, H, B
PTX-0055						DiMasi et al., "The price of innovation: new estimates of drug development costs," J. Health Econ. 22:151-185 (2003)	ABB_SIM 00898844 - ABB_SIM 00898879	RM , H
PTX-0056						DiMasi et. al., Tufts Center for the Study of Drug Development, Impact Report, "Post-approval R&D raises total drug development costs to $897 million," Vol. 5, No. 3 (May/June 2003)	ABB_SIM 00696032 - ABB_SIM 00696035	A, F, R, C, P, H, B
PTX-0057						Drugs@FDA Glossary of Terms, available at www.fda.gov/Drugs/informationondrugs/ucm079436		A, F, R, C, P, H, B, I, NP
PTX-0058						Dube, et al. "Safety and efficacy of extended-release niacin for the treatment of dyslipidaemia in patients with HIV infection: AIDS Clinical Trials Group Study A5148," Antiviral Therapy. 2006; 11:1081-1089	ABB_SIM 00566512 - ABB_SIM 00566520	A, F, R, C, P, H, B
PTX-0061						FDA Guidance for Industry: Statistical Approaches to Establishing Bioequivalence (January 2011)	ABB_SIM 00695964 - ABB_SIM 00696011	A, F, R, C, P, H, B, I, NP

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PTX-0062						FDA Guidance for Industry: SUPAC-MR: Modified Release Solid Oral Dosage Forms	ABB_SIM 00944555 - ABB_SIM 00944606	A, F, R, C, P, H
PTX-0063						Food & Drug Administration, ANDA Labeling Review, available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072891.pdf		A, F, R, C, P, H, B, I, NP
PTX-0064						Food & Drug Administration, ANDA, available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm		A, F, R, C, P, H, B, I, NP
PTX-0065						Food & Drug Administration, CDER Data Standards Manual, available at http://www.fda.gov/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/default.htm		A, F, R, C, P, H, B, I, NP
PTX-0066						Food & Drug Administration, Center for Drug Evaluation & Research, "Guidance for Industry Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations." March 2003	ABB_SIM 00573340 - ABB_SIM 00573365	RM , H
PTX-0067						Food & Drug Administration, Center for Drug Evaluation & Research, Guidance for Industry: Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations, at 10-11 (March 2003); available at http://fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/usm070124.pdf		A, F, R, C, P, H, B, I, NP
PTX-0068						Food & Drug Administration, Center for Drug Evaluation & Research, Guidance for Industry: Food-Effect Bioavailability and Fed Bioequivalence Studies (Dec. 2002), available at http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126833.pdf		A, F, R, C, P, H, B, I, NP

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PTX-0069						Food & Drug Administration, Center for Drug Evaluation & Research, Guidance for Industry: Statistical Approaches for Establishing Bioequivalence (Jan. 2001), available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070244.pdf		A, F, R, C, P, H, B, I, NP
PTX-0070						Food & Drug Administration, New Drug Application (NDA) Process, available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm		A, F, R, C, P, H, B, I, NP
PTX-0071						Food & Drug Administration, Revising ANDA Labeling Following Revision of the RLD Labeling (May 2000), available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm072891.pdf	ABB_SIM 00696016 - ABB_SIM 00696021	A, F, R, C, P, H, B
PTX-0072						Food & Drug Administration, The CDER Handbook: Labeling Review Acceptable?	ABB_SIM 00695122 - ABB_SIM 00695205	A, F, R, C, P, H, B
PTX-0073						Frick, et al,, “Helsinki Heart Study: Primary-prevention trial with gemfibrozil middle-aged men with dyslipidemia: Safety of treatment, changes in risk factors, and incidence of coronary heart disease,” N ENGL J MED 1987:317:1237-1245	ABB_S2_00159796 - ABB_S2_00159804	A, F, R, C, P, H, B
PTX-0075						Garrison, “Cigarette smoking and HDL cholesterol: The Framingham Offspring Study,” ATHEROSCLEROSIS, Vol. 30, Issue 1: 17-25 (May 1978)	ABB_S2_00158266 - ABB_S2_00158274	A, F, R, C, P, H, B
PTX-0076						Goldberg, et al. "Multiple-Dose Efficacy and Safety of an Extended-Release Form of Niacin in the Management of Hyperlipidemia," Am J Cardiol. 2000; 85:1100-1105	ABB_SIM 00566521 - ABB_SIM 00566526	A, F, R, C, P, H, B
PTX-0077						Gordon, et al., "High Density Lipoprotein As a Protective Factor Against Coronary Heart Disease", The American Journal of Medicine, Volume 62, May 1977	ABB_SIM 00414956 - ABB_SIM 00414963	A, F, R, C, P, H, B
PTX-0078						Gordon, et al., “High-density lipoprotein cholesterol and coronary heart disease in hypercholesterolemic men: The Lipid Research Clinics Coronary Primary Prevention Trial,” CIRCULATION, 1986:74:1217-1225	ABB_SIM 00573124 - ABB_SIM 00573133	A, F, R, C, P, H, B

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PTX-0081						Guyton, "Extended-release niacin for modifying the lipoprotein profile," Expert Opin. Pharmacother. 2004; 5(6):1385-1398	ABB_SIM 00566536 - ABB_SIM 00566549	A, F, R, C, P, H, B
PTX-0082						Guyton, et al. "A Symposium: New Advances in Dyslipidemia," The American Journal of Cardiology, December 17, 1988	ABB_S2_00161505 - ABB_S2_00161599	A, F, R, C, P, H, B
PTX-0083						Handbook of Pharmaceutical Excipients, Second Edition, pp. 229-32, 280-82, 392-99, 494-97 (1994)		RM , H
PTX-0086						Heron, et al., "National Vital Statistics Report: Deaths: Final Data for 2006," 57:14 (Apr. 17, 2009)	ABB_SIM 00695249 - ABB_SIM 00695383	A, F, R, C, P, H, B
PTX-0087						Huskamp et al., "The New Medicare Drug Benefit: Formularies and Their Potential Effects on Access to Medications" HEALTH POLICY PERSPECTIVES, 2005		A, F, R, C, P, H, B, I, NP
PTX-0088						J.B.D.L. Corp., d/b/a Beckett Apothecary, et al. v. Wyeth-Ayerst Laboratories, Inc., et al., No. 1:01-cv-704, 1:03-cv-781, June 13, 2005		A, F, R, C, P, H, NP
PTX-0089						Jianqiu Pan et al. Extended-Release Niacin Treatment of the Atherogenic Lipid Profile and Lipoprotein(a) in Diabetes, Metabolism. 2002; 51(9):1120-1127	ABB_SIM 00566662 - ABB_SIM 00566669	A, F, R, C, P, H, B
PTX-0090						Kaiser Family Foundation report, June 2003, Impact of Direct-to-Consumer Advertising on Prescription Drug Spending (http://www.kff.org/rxdrugs/6084-index.cfm)	ABB_SIM 01197166 - ABB_SIM 01197176	A, F, R, C, P, H, B
PTX-0091						Kane et al. , "Treatment of Hypercholesterolemia," Medical Clinics of North America - Vol. 66, No. 2, March 1982		A, F, R, C, P, H, B, NP
PTX-0093						Karas, et al., "Incidence of Flushing Decreases Over Time During Long-Term Therapy with a Novel Combination of Niacin Extended-Release with Simvastatin," Journal of Clinical Lipidology, Vol. 2, No. 3, June 2008		A, F, R, C, P, H, B, S, I
PTX-0094						Karas, et al., "Long-Term Safety and Efficacy of a Combination of Niacin Extended Release and Simvastatin in Patients with Dyslipidemia,", Am J Cardiovasc Drugs, 2008; 8 (2): 69-81	ABB_SIM 00270061 - ABB_SIM 00270073	A, F, R, C, P, H, B

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PTX-0095						Kaushik et al., “Extended-release niacin decreases serum fetuin-A concentrations in individuals with metabolic syndrome,” Diabetes Metab Res Rev. 2009; 25:427-434	ABB_SIM 00566574 - ABB_SIM 00566581	A, F, R, C, P, H, B
PTX-0096						Keenan, "A Physicians Guide to Niacin Therapy"	ABB_SIM 01263150 - ABB_SIM 01263154	A, F, R, C, P, H, B, I
PTX-0097						Kesala, et al., “Niacin (N) vs. Niaspan (NS) Treatment of the Atherogenic Lipid Profile (ALP; Small, Dense LDL, HDL2, HDLc and Triglycerides) and Lp(a) in Diabetic Patients (DP),” Abstract	ABB_S2_00152370	A, F, R, C, P, H, B, I, S
PTX-0099						Knopp, “Clinical Profiles of Plain Versus Sustained-Release Niacin (Niaspan) and the Physiologic Rationale for Nighttime Dosing,” Am J Cardiol. 1998; 82(12A):24U-28U.	ABB_SIM 00566740 - ABB_SIM 00566744	A, F, R, C, P, H, B
PTX-0101						Knopp, “Niacin and Hepatic Failure” Annals of Internal Medicine 1989; 111(9):764-769.	ABB_SIM 00566734 - ABB_SIM 00566739	A, F, R, C, P, H, B
PTX-0103						Kolter, "Binding Properties of the New Polymer Kollicoat IR," Development Pharma Ingredients, BASF Aktiengesellschaft, available at http://www.aapsj.org/abstracts/AM_2002/AA{2002-000995.pdf		A, F, R, C, P, H, B, NP, I, S
PTX-0104						Lachman, "Chapter 14, Sustained Action Dosage Forms," The Theory and Practice of Industrial Pharmacy, Second Edition	ABB_SIM 01099911 - ABB_SIM 0109939	A, F, R, C, P, H, B
PTX-0105						Lachman, "The Theory and Practice of Industrial Pharmacy," pp. 320-21 (3d ed. 1986)		A, F, R, C, P, H, B, NP, I
PTX-0106						Lamon-Fava et al., Extended-Release Niacin Alters the Metabolism of Plasma Apolipoprotein (Apo) A-I and ApoB-Containing Lipoproteins, Arterioscler Thromb Vasc Biol. 2008; 28:1672-1678.	ABB_SIM 00566596 - ABB_SIM 00566604	A, F, R, C, P, H, B
PTX-0107						Lawrence, “Transient Focal Hepatic Defects Related to Sustained-Release Niacin,” J Clin Gastroenterol. 1993; 16(3):234-236	ABB_SIM 00566866 - ABB_SIM 00566869	A, F, R, C, P, H
PTX-0108						Mahley, et al., "Drug Therapy For Hypercholesterolemia and Dyslipidemia," Goodman & Gilman's The Pharmacological Basis of Therapeutics, Eleventh Edition	ABB_SIM 00696151 - ABB_SIM 00696186	A, F, R, C, P, H, B

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PTX-0109						Mann, "Medical Intelligence Current Concepts - Diet-Heart: End of an Era", The New England Journal of Medicine September 22, 1977	ABB_SIM 01167515 - ABB_SIM 01167521	A, F, R, C, P, H, B
PTX-0110						Manninen, et al., "Gemfibrozil in the Treatment of Dyslipidemia A 5 year follow-up study", Acta Med Scand (Supp) (1982)	ABB_SIM 01167345 - ABB_SIM 01167351	A, F, R, C, P, H
PTX-0111						Manninen, et al., "Joint Effects of Serum Triglyceride and LDL Cholesterol and HDL Cholesterol Concentrations on Coronary Heart Disease Risk in the Helsinki Heart Study: Implications for Treatment," CIRCULATION, Vol. 85, No. 1 (Jan. 1992)	ABB_SIM 00033229 - ABB_SIM 00033237	A, F, R, C, P, H, B
PTX-0112						Manninen, et al., "Lipid alterations and decline in the incidence of coronary heart disease in the Helsinki Heart Study," JAMA 1988:260:641-51	ABB_SIM 00033218 - ABB_SIM 00033228	A, F, R, C, P, H, B
PTX-0113						Manttari, et al, "The Helsinki Heart Study: Basic design and randomization procedure," EUR HEALTH J, 1987:8 (suppl 1):1-29	ABB_SIM 00573134 - ABB_SIM 00573164	A, F, R, C, P, H, B
PTX-0114						Marshall, et al., "Development of a Compendial Taxaonomy and Glossary for Pharmaceutical Dosage Forms", 29 Pharmacopeial Forum 1749 (September-October 2003)	ABB_SIM 00696187 - ABB_SIM 00696199	A, F, R, C, P, H, B
PTX-0115						McCormack, et al., "Prolonged-Release Nicotinic Acid: A Review of its Use in the Treatment of Dyslipidaemia," Drugs 2005; 65(18):2719-2740	ABB_SIM 00566605 - ABB_SIM 00566626	A, F, R, C, P, H, B
PTX-0116						McGovern, "Use of nicotinic acid in patients with elevated fasting glucose, diabetes, or metabolic syndrome," Br. J. Diabetes (2004)	ABB_S2_00567305 - ABB_S2_00567312	A, F, R, C, H, B, I
PTX-0117						McKenney et al., "A Comparison of the Efficacy and Toxic Effects of Sustained- vs. Immediate-Release Niacin in Hypercholesterolemic Patients, JAMA, Vol. 271, No. 9, March 2, 1994, O'Neill Ex 113	TV0047178 - TV0047184	A, F, R, H
PTX-0118						McMichael, "Fats and Atheroma: An Inquest", British Medical Journal, 1979	ABB_SIM 01170346 - ABB_SIM 01170348	A, F, R, H, B
PTX-0119						Menon, et al. "Effect of the Rate of Niacin Administration on the Plasma and Urine Pharmacokinetics of Niacin and Its Metabolites," J Clin Pharmacol 2007; 47:681-688	ABB_SIM 00566627 - ABB_SIM 00566635	A, F, R, H, B

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PTX-0120						Menon, et al., “Plasma and urine pharmacokinetics of niacin and its metabolites from an extended-release niacin formulation,” International Journal of Clinical Pharmacology and Therapeutics 2007; 45(8):448-454	ABB_SIM 00566875 - ABB_SIM 00566881	A, F, R, H, B
PTX-0121						Merck & Co, “Merck to Launch TREDAPTIVE (ER niacin/laropiprant) in international Markets Later This Year,” May 19, 2009	ABB_SIM 00573297 - ABB_SIM 00573298	A, F, R, C, P, H, B
PTX-0122						Meyers, et al., "Varying Cost and Free Nicotinic Acid Content in Over-the-Counter Niacin Preparations for Dyslipidemia," Ann Intern Med. 2003, 139.966-1002	ABB_S2_00868397 - ABB_S2_00868405	A, F, R, H, B
PTX-0123						Michael E. Winter, Basic Clinical Pharmacokinetics (5th ed. 2010)		A, F, R, H, C
PTX-0124						Miller, “Association of high-density lipoprotein subclasses and apolipoproteins with ischemic heart disease and coronary artherosclerosis,” AM HEART J, 1987:113:589-597	ABB_SIM 00573169 - ABB_SIM 00573178	A, F, R, H
PTX-0125						Miller, et al., “Triglycerides and Cardiovascular Disease,” American Heart Association Scientific Statement 123, 2292-2333 (2011)	ABB_SIM 01262901 - ABB_SIM 01262943	A, F, R, H
PTX-0126						Mizik, et al., “Are Physicians ‘Easy Marks?’: Quantifying the Effects of Detailing and Sampling on New Prescriptions,” Management Science 50(12): 1704-15 (2004)	ABB_SIM 01197607 - ABB_SIM 01197620	A, F, R, H, B
PTX-0127						Moore, et al., "Mathematical Comparison of Dissolution Profiles", Pharmaceutical Technology, June 1996	ABB_SIM 00540411 - ABB_SIM 00540416	A, F, R, H, B, C, P
PTX-0128						Morgan et al. A New Extended-Release Niacin (Niaspan): Efficacy, Tolerability, and Safety in Hypercholesterolemic Patients, Am J Cardiol. 1998; 82(12A):29U-34U	ABB_SIM 00566645 - ABB_SIM 00566650	A, F, R, H, B
PTX-0129						Morgan et al. Effects of Extended-Release Niacin on Lipoprotein Subclass Distribution, Am J Cardiol. 2003; 91:1432-1436	ABB_SIM 00566651 - ABB_SIM 00566655	A, F, R, H, B
PTX-0131						Muller et al., Niacin Lowers Serum Phosphate and Increases HDL Cholesterol in Dialysis Patients, Clin J Am Soc Nephrol. 2007; 2:1249-1254	ABB_SIM 00566656 - ABB_SIM 00566661	A, F, R, H, B

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PTX-0133						National Heart Lung and Blood Institute's Lipid Research Clinics Program: The Lipid Research Clinics Coronary Primary Prevention Trial Results: I. Reduction in incidence of coronary heart disease, JAMA 1984; Vol. 251, No. 3, 351-64	ABB_SIM 00041747 - ABB_SIM 00041760	A, F, R, H, B
PTX-0134						National Heart Lung and Blood Institute's Lipid Research Clinics Program: The Lipid Research Clinics Coronary Primary Prevention Trial Results: II. The Relationship of Reduction in Incidence of Coronary Heart Disease to Cholesterol Lowering, JAMA 1984, Vol. 251, No. 3, 365-74	ABB_SIM 00033453 - ABB_SIM 00033462	A, F, R, H, B
PTX-0135						Oliver, "Serum Cholesterol - The Knave of Hearts and the Joker", The Lancet, November 14, 1981	ABB_SIM 01167522 - ABB_SIM 01167527	A, F, R, H, B
PTX-0136						Orange Book Preface, available at http://www.fda.gov/drugs/developmentapprovalprocess/ucm079068.htm		A, F, R, H, C, P
PTX-0137						Padley, et al., "History of Asprin Use Prior to Initiation of Combination Niacin Extended-Release & Simvastatin Therapy Reduces Flushing-Related Discontinuation Rates"	ABB_SIM 00270084	A, F, R, H, C, P, B, S
PTX-0138						Palumbo, “Rediscovery of Crystalline Niacin,” Mayo Clin Proc. 1991; 66:112-113	ABB_SIM 00566873 - ABB_SIM 00566874	A, F, R, H, C, P, B, ID
PTX-0139						Pan, et al., "Extended-Release Niacin Treatment of the Atherogenic Lipid Profile and Lipoprotein(a) in Diabetes", Diabetes Research Center (2001)	ABB_S2_00229540 - ABB_S2_00229547	A, F, R, H, B
PTX-0140						Pan, et al., "Niacin treatment of the atherogenic lipid profile and Lp(a) in diabetes,", Diabetes, Obesity and Metabolism, 4, 2002, 255-261	ABB_S2_00229533 - ABB_S2_00229539	A, F, R, H, B
PTX-0141						Perry, “ADIS Drug Profile: Extended-Release Niacin (Nicotinic Acid)/Laropiprant,” Drugs 2009:69(12)1665-1679	ABB_SIM 00944204 - ABB_SIM 00944220	A, F, R, H
PTX-0142						Peters, et al., Quantitative Clinical Chemistry, 2nd ed., The Williams & Wilkins Co., Baltimore (1946)	ABB_SIM 01168756 - ABB_SIM 01168759	A, F, R, H
PTX-0143						Khankari et al., “Binders and Solvents,” Handbook of Pharmaceutical Granulation Technology, 1st ed., p. 60 (1997)		A, F, R, H, NP

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PTX-0144						Kotler and Armstrong, Principles of Marketing, (10th ed. 2004)	ABB_SIM 00899266 - ABB_SIM 00899270	A, F, R, H, I
PTX-0145						Physicians' Desk Reference (44th Ed. 1990)	ABB_SIM 01262899 - ABB_SIM 01262900	A, F, R, H, I, C, P
PTX-0147						Pipeline Insight: Dyslipidemia, April 2007	ABB_S2_02202801 - ABB_S2_02202950	A, F, R, H, C, P
PTX-0148						Poldermans et al., Prolonged-Release Nicotinic Acid in Patients with Atherosclerotic Disease in The Netherlands, Eur Surg Res. 2008; 41:313-318	ABB_SIM 00566670 - ABB_SIM 00566675	A, F, R, H
PTX-0149						Public Citizen Health Research v. National Institutes of Health, No. Civ.A. 00-1847(CKK), March 12, 2002		A, F, R, C, H, NP
PTX-0151						Remington's Pharmaceutical Sciences (1985) at 1605-06		A, F, R, H
PTX-0152						Robinson et al., "The Antilipidemic Effects of Plain and Extended-Release Niacin," Prev. Cardiol. 2000; 3:131-136.	ABB_SIM 00566908 - ABB_SIM 00566913	A, F, R, H
PTX-0153						Robinson, "Changing the Face of Detailing by Motivating Physicians to See Pharmaceutical Sales Reps," Product Management Today, Nov. 2003	ABB_SIM 01197621 - ABB_SIM 01197628	A, F, R, H, I
PTX-0154						Rowland, et al., "Clinical Pharmacokinetics: Concepts and Applications," pg. 111 (1980)	ABB_S2_00225286 - ABB_S2_00225288	A, F, R, H, I
PTX-0155						Rubin, P. H., "The Economics and Impact of Pharmaceutical Promotion," Economic Realities of Healthcare Policy, 3(1): 6-19 (2003)	ABB_SIM 00696204 - ABB_SIM 00696219	A, F, R, H, C
PTX-0156						Rubins, et al., "Gemfibrozil for the secondary prevention of coronary heart disease in men with low levels of HDL cholesterol," N Eng J Med 1999;341:410-8	ABB_S2_00071774 - ABB_S2_00071783	A, F, R, H
PTX-0157						Rubins, et al., "Rationale and design of the Dept. of Veterans Affairs High-density lipoprotein cholesterol Intervention Trial (HIT) for secondary prevention of coronary artery disease in men with low HDL and desirable LDL," Am J Cardiol 1993;71:45-52	ABB_S2_00077614 - ABB_S2_00077621	A, F, R, H
PTX-0158						Rubins, et al., "Veterans Affairs High-Density Lipoprotein Cholesterol Intervention Trial (HIT) for Secondary Prevention of Coronary Artery Disease in Men with Low High-Density Lipoprotein Cholesterol and Desirable Low-Density Lipoprotein Cholesterol," Jan. 1, 1993	ABB_SIM 00573299 - ABB_SIM 00573307	A, F, R, H

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PTX-0159						Ryan, et al., Dept of Health, Education, and Welfare "The Belmont Report," available at: http://www.hhs.gov/ohrp/humansubjects/guidance/Belmont.html	ABB_SIM 00696027 - ABB_SIM 00696031	A, F, R, H, I, C, P
PTX-0160						Sacks, "The Role of High-Density Lipoprotein (HDL) Cholesterol in the Prevention and Treatment of Coronary Heart Disease: Expert Group Recommendations," 90 Am. J. Cardiol. 2002;90:139-143.	ABB_SIM 00573254 - ABB_SIM 00573258	A, F, R, H, B
PTX-0161						Sacks, et al., "Effect on coronary artherosclerosis of decrease in plasma cholesterol concentrations in normocholesterolaemic patients," THE LANCET, Vol. 344, 1182-86 (Oct. 29, 1994)	ABB_SIM 00573249 - ABB_SIM 00573253	A, F, R, H, B
PTX-0162						Shah, et al., "In Vitro Dissolution Profile Comparison - Statistics and Analysis of the Similarity Factor, f2", Pharmaceutical Research, Vol. 15, No. 6, 1998	ABB_SIM 00551692 - ABB_SIM 00551699	A, F, R, H, B
PTX-0163						Shargel, et al., "Applied Biopharmaceutics and Pharmacokinetics," Third Edition	ABB_SIM 00944282 - ABB_SIM 00944376	A, F, R, H, B, C
PTX-0164						Shaw, "Direct-to-Consumer Advertising (DTC) of Pharmaceuticals, ProQuest Discovery Guides," (March 2008) www.csa.com/discoveryguides/discoveryguides-main.php		A, F, R, H, B, I, C
PTX-0165						Stedman's Medical Dictionary, Fifth Unabridged Lawyers' Edition, (1982)	ABB_SIM 00535267 - ABB_SIM 00535270	A, F, R, H, B
PTX-0166						Superko et al., "Differential Effect of Two Nicotinic Acid Preparations on Low-Density Lipoprotein Subclass Distribution in Patients Classified as Low-Density Lipoprotein Pattern A, B, or I.," Am. J. Cardiol. (2004)	ABB_S2_01107914 - ABB_S2_01107920	A, F, R, H, B
PTX-0167						Tavintharan, et al., "The Benefits of Niacin in Atherosclerosis," Current Atherosclerosis Reports 2001; 3:74-82	ABB_SIM 00566683 - ABB_SIM 00566691	A, F, R, H, B
PTX-0168						The Coronary Drug Project Research Group, Clofibrate and Niacin in Coronary Heart Disease, JAMA. 1975;231:360-381	ABB_S2_00169356 - ABB_S2_00169377	A, F, R, H, B
PTX-0169						USP XXII The United States Pharmacopeia, January 1, 1990		RM , H

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PTX-0170						Venkataraman & Stremersch, "The Debate on Influencing Doctors' Decisions: Are Drug Characteristics the Missing Link?," Management Science, 53(11) 1688-1701 (2007)	ABB_SIM 01197660 - ABB_SIM 01197674	A, F, R, H, B, I
PTX-0171						Vogt et al. "Evaluation of the safety and tolerability of prolonged-release nicotinic acid in a usual care setting: the NAUTILUS study," Curr Med Res Opin. 2006; 22(2):417-425	ABB_SIM 00566692 - ABB_SIM 00566700	A, F, R, H, B
PTX-0172						Vogt et al., "Prolonged-release nicotinic acid for the management of dyslipidemia: an update including results from the NAUTILUS study," Vascular Health and Risk Management 2007; 3(4):467-479.	ABB_SIM 00566709 - ABB_SIM 00566721	A, F, R, H, B
PTX-0173						Vogt, et al., "Correction of low HDL cholesterol to reduce cardiovascular risk: practical considerations relating to the therapeutic use of prolonged-release nicotinic acid (Niaspan)," Int J Clin Pract. 2007; 61(11):1914-1921	ABB_SIM 00566701 - ABB_SIM 00566708	A, F, R, H, B
PTX-0174						Wilson, et al., "Factors associated with lipoprotein cholesterol levels: The Framingham Study," ARTERIOSCLEROSIS, Vol. 3, 273-281 (1983)	ABB_SIM 00573308 - ABB_SIM 00573317	A, F, R, H, B
PTX-0175						Wolfe, et al.. "Safety and Effectiveness of Niaspan When Added Sequentially to a Statin for Treatment of Dyslipidemia," Am J Cardiol. 2001; 87:476-479.	ABB_SIM 00566722 - ABB_SIM 00566725	A, F, R, H, B
PTX-0555						UNITED STATES PHARMACOPIEA - DRUG INFORMATION, VOL. I, Drug Information for the Healthcare Professional (U.S. Pharmacopeia Convention, Inc., 1993) pp. 2021-2025		
						CORRESPONDENCE		
PTX-0176						Letter dated January 19, 2011 from Berg to Evenstad re Warning Letter	ABB_SIM 01259614 - ABB_SIM 01259615	A, F, R, H, B
PTX-0183						Facsimile cover sheet dated August 21, 1996 from E. Cefali to P. Jones re Niaspan Dissolution F2 Analysis	ABB_SIM 00566761 - ABB_SIM 00566767	A, F, R, H, B
PTX-0190						Memorandum dated August 20, 1997 from S. Jenkins to M. Blanford, et al. re: Dissolution Profile Differences for Edison Niaspan Tablets	ABB_S2_00076762	A, F, R, H, B
PTX-0194						Email dated November 23, 1999 from M. McGovern to J. Phillips re: Harvard Health Letter	ABB_S2_00155529	A, F, R, H, B

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PTX-0195						Letter dated August 24, 2001 from D. Warnock to D. Orloff re Advicor IND 56,027, Annual Report 2000-2001	ABB_SIM 00742884 - ABB_SIM 00743177	A, F, R, H, B
PTX-0196						Letter dated April 17, 2007 from J. Fox to M. Parks re: Original New Drug Application: NDA 22-078 (Simcor)	ABB_SIM 00076428 - ABB_SIM 00076434	A, F, R, H, B
PTX-0198						Letter dated November 20, 2009 from T. Verciglio to Dr. M. Parks re: Niacin Extended-Release/Simvastatin (Simcor) Tablets NDA 22-078 eCTD Sequence 0027	ABB_SIM 00295989 - ABB_SIM 00295998	A, F, R, H, B
PTX-0199						Letter from E. Colman to T. Verciglio re NDA 22-078/S-006, S-007 Supplement Approval	ABB_SIM 00734349 - ABB_SIM 00734401	A, F, R, H, B
NDA/CLINCIAL DOCUMENTS								
PTX-0202						Final Report, Protocol 016-06-05-CP, December 5, 2005	ABB_S2_00721724 - ABB_S2_00722912	A, F, R, H, I
PTX-0203						3.2.P.2.2 Nicotinic acid 375 mg, 500 mg, 750 mg and 1000 mg prolonged release tablet drug development	ABB_S2_01065962 - 1ABB_S2_0065987	A, F, R, H, I
PTX-0204						Final Report, Protocol 016-02-04-CP	ABB_S2_02922855 - ABB_S2_02923235	A, F, R, H, I
PTX-0205						NDA 20-381, Niaspan Controlled-Release Tablets, Chemistry, Manufacturing, Controls	ABB_SIM 00003295 - ABB_SIM 00003589	A, F, R, H, I
PTX-0206						Letter dated May 16, 1996 from E. Galliers to D. Bova	ABB_S2_00000032	A, F, R, H, I
PTX-0207						Letter dated May 3, 1996 from D. Bova to the Food and Drug Administration Center for Drugs and Biologics	ABB_S2_00000033 - ABB_S2_00000034	A, F, R, H, I
PTX-0208						Application to Market a New Drug for Human Use or an Antibiotic Drug for Human Use for Niacin Sustained-Release Tablets (Niaspan) dated May 3, 1996	ABB_S2_00000037 - ABB_S2_00000245	A, F, R, H, I
PTX-0209						Clinical Study Report 91/19; NDA 20-381, Volume 3.23	ABB_S2_00006017 - ABB_S2_00006351	A, F, R, H, I
PTX-0210						Reference Volume - Articles from Literature; NDA 20-381, Volume 3.27	ABB_S2_00007296 - ABB_S2_00007514	A, F, R, H, I
PTX-0211						A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan in Patients with Primary Hyperlipoproteinemia - A Dose-Ranging Study, Protocol No. 91/05, January 13, 1992	ABB_S2_00012106 - ABB_S2_00012152	A, F, R, H, I
PTX-0212						Clinical Study 91/09 Appendices; NDA- 20-381, Volume 3.65	ABB_S2_00019500 - ABB_S2_00019867	A, F, R, H, I
PTX-0214						NDA 20-381, Volume 3.76	ABB_S2_00023217 - ABB_S2_00023395	A, F, R, H, I
PTX-0215						NDA 20-381, Vol. 3.77	ABB_S2_00023396 - ABB_S2_00023719	A, F, R, H, I

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PTX-0218						Protocol Number 91/02, A Pilot Efficacy Study of a Once-A-Day Sustained Release Niacin Formulation (Niaspan) in the Treatment of Primary Type IIa Hyperlipidemia, January 31, 1991	ABB_S2_00025574 - ABB_S2_00025596	A, F, R, H, I
PTX-0219						Preliminary Results From Study 91/02 Dosing 1500 MGS of Niaspan Once-a-Day	ABB_S2_00025647 - ABB_S2_00025648	A, F, R, H, I
PTX-0220						Study Protocol 91/04	ABB_S2_00025668 - ABB_S2_00025727	A, F, R, H, I
PTX-0221						A Double-Blind Placebo Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan (sustained released niacin) in Patients with Primary Hyperlipoproteinemia, Protocol Number 91/05, Aug. 23, 1991	ABB_S2_00025728 - ABB_S2_00025781	A, F, R, H, I
PTX-0222						Summary of Data Obtained From Patients Receiving 1500 mg of Niaspan Once-A-Day At Night (Studies 89/04 and 91/02)	ABB_S2_00026126 - ABB_S2_00026140	A, F, R, H, I, S
PTX-0223						Application To Market a New Drug, Biologic, or An Antibiotic Drug for Human Use for Niacin Extended-Release Tablets, September 29, 1998	ABB_S2_00035730 - ABB_S2_00036258	A, F, R, H, I
PTX-0224						NDA 20-381, September 2000, Annual Report, Appendix 3, Study 91/09	ABB_S2_00043357 - ABB_S2_00043802	H
PTX-0225						A Three-Way Crossover Study of the Bioavailability of Niacin From a Sustained release Formulation When Dosed in the Fed Versus Fasted States in Reference to an Immediate Release Formulation, Protocol No. 91/01, June 3, 1991	ABB_S2_00076940 - ABB_S2_00077040	A, F, R, H, I
PTX-0226						NDA 20-381, Volume Number 2.24	ABB_S2_00089340 - ABB_S2_00089676	A, F, R, H, I
PTX-0227						NDA 20-381, Volume Number 2.34	ABB_S2_00091844 - ABB_S2_00092213	A, F, R, H, I
PTX-0228						NDA 20-381, Volume Number 2.35	ABB_S2_00092214 - ABB_S2_00092546	A, F, R, H, I
PTX-0229						NDA 20-381, Volume Number 2.36	ABB_S2_00092547 - ABB_S2_00092711	A, F, R, H, I
PTX-0230						NDA 20-381, Volume Number 2.37	ABB_S2_00092712 - ABB_S2_00093156	A, F, R, H, I
PTX-0231						NDA 20-381, Volume Number 2.38	ABB_S2_00093157 - ABB_S2_00093436	A, F, R, H, I
PTX-0232						NDA 20-381, Volume Number 2.39	ABB_S2_00093437 - ABB_S2_00093852	A, F, R, H, I
PTX-0233						Appendices to Final Study Report 91/04, NDA 20-381, Volume Number 2.40	ABB_S2_00093853 - ABB_S2_00094291	A, F, R, H, I
PTX-0235						NDA 20-381, Volume Number 2.42	ABB_S2_00094785 - ABB_S2_00095165	A, F, R, H, I
PTX-0236						NDA 20-381, Volume Number 2.43	ABB_S2_00095166 - ABB_S2_00095314	A, F, R, H, I
PTX-0237						NDA 20-381, Volume Number 2.44	ABB_S2_00095315 - ABB_S2_00095659	A, F, R, H, I
PTX-0238						NDA 20-381, Volume Number 2.45	ABB_S2_00095660 - AABB_S2_00096091	A, F, R, H, I

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PTX-0239						Niaspan Sustained-Release Tablets, NDA 20-381, Volume Number 2.48	ABB_S2_00096648 - ABB_S2_00097147	A, F, R, H, I
PTX-0240						Niaspan Sustained-Release Tablets, NDA 20-381, Volume Number 2.49	ABB_S2_00097148 - ABB_S2_00097594	A, F, R, H, I
PTX-0241						Niaspan Sustained-Release Tablets, NDA 20-381, Volume Number 2.50	ABB_S2_00097595 - ABB_S2_00098184	A, F, R, H, I
PTX-0242						Final Report for 91/02, A Pilot Efficacy Study of Once-a-Day Sustained-Release Niacin Formulation (Niaspan) in the Treatment of Primary Type IIa Hyperlipidemia	ABB_S2_00118698 - ABB_S2_00118707	A, F, R, H, I
PTX-0243						Protocol 94/07 Comparison of the Effects of Two Sustained-Release Niacin Formulations on Serum Phosphorus (May 24, 1994)	ABB_S2_00181987 - ABB_S2_00182015	A, F, R, H, I
PTX-0245						A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan in Patients with Primary Hyperlipoproteinemia, Protocol 91/04	ABB_S2_00187914 - ABB_S2_00187991	A, F, R, H, I
PTX-0246						A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan in Patients with Primary Hyperlipoproteinemia, Jan. 13, 1992	ABB_S2_00187917 - ABB_S2_00187967	A, F, R, H, I
PTX-0247						Proposed Clinical Studies to be Submitted in Support of a New Drug Application for Once-a-Day Niaspan in the Treatment of Primary Hyperlipoproteinemia, Clinical Development Plan, July 22, 1991	ABB_S2_00191444 - ABB_S2_00191452	A, F, R, H, I
PTX-0249						Kos Pharmaceuticals, Niaspan F2 Report prepared by Arthur Straughn	ABB_S2_00233927 - ABB_S2_00233971	A, F, R, H, I
PTX-0250						Niacin Dissolution Report for Niaspan 1000mg DC Core Tab. Diss.	ABB_S2_00748463	A, F, R, H, I
PTX-0251						Dissolution Niacin ER 1000mg Ave. of 6 Tabs	ABB_S2_00748673	A, F, R, H, I
PTX-0252						Niacin Dissolution Report for Niaspan 1000mg ER Core Tab. Diss.	ABB_S2_00748675	A, F, R, H, I
PTX-0253						Testing data Niaspan 1000 mg DC Dissolution	ABB_S2_00749198	A, F, R, H, I
PTX-0254						Dissolution Niacin ER 1000mg Ave. of 6 Tabs	ABB_S2_00749199	A, F, R, H, I
PTX-0255						Niacin Dissolution Report for Niaspan 1000mg DC Core Tab. Diss.	ABB_S2_00749206	A, F, R, H, I
PTX-0257						Final Report for The Comparative Bioequivalence of Reformulated 1000 mg Extended - Release Niacin Tablets versus 1000 mg Niaspan Tablets Administered as a Single 2000 mg Dose to Healthy Volunteers, March 31, 2006	ABB_S2_02920439 - ABB_S2_02921637	A, F, R, H, I

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PTX-0258						M10-414 Clinical Study Report "Comparison of Bioavailability of 1000 mg Niacin Extended Release Tablet Manufactured at Abbott Puerto Rico Plan Relative to the Manufactured at Abbott New Jersey Plant, December 16, 2008	ABB_S2_03450295 - ABB_S2_02452016	A, F, R, H, I
PTX-0259						Food and Drug Administration Application to Market A New Drug For Human Use or an Antibiotic Drug for Human Use, Niaspan Sustained-Release Tablets	ABB_SIM 00003086 - ABB_SIM 00003294	A, F, R, H, I
PTX-0260						NDA 20-381, Vol. 3.7, Final Report 89/03	ABB_SIM 00004605 - ABB_SIM 00004693	A, F, R, H, I
PTX-0262						Final Study Reports for Clinical Studies 94/09	ABB_SIM 00005055 - ABB_SIM 00005108	A, F, R, H, I
PTX-0263						Kos Pharmaceuticals, Inc., NDA 20-381, Niaspan Controlled-Release Tablets, Human Pharmacokinetics and Bioavailability, Volume Contents - Volume 3.10	ABB_SIM 00005421 - ABB_SIM 00005751	A, F, R, H, I
PTX-0264						Kos Pharmaceuticals, Inc., NDA 20-381, Niaspan Controlled-Release Tablets, Human Pharmacokinetics and Bioavailability, Volume Contents - Volume 3.11	ABB_SIM 00005752 - ABB_SIM 00006133	A, F, R, H, I
PTX-0265						Final Study Reports for Clinical Studies 95/01	ABB_SIM 00005754 - ABB_SIM 00005791	A, F, R, H, I
PTX-0266						Kos Pharmaceuticals, Inc., November 7, 1995, Protocol # 95/01, Final Report	ABB_SIM 00006135 - ABB_SIM 00006285	A, F, R, H, I
PTX-0267						NDA 20-381, Vol. 3.15, The Effect of Manufacturing Variables on the Bioavailability of Niaspan 1000mg Tablets, Protocol 95/05 Interim Report, Feb. 16, 1996	ABB_SIM 00006792 - ABB_SIM 00007029	A, F, R, H, I
PTX-0268						Final Study Reports for Clinical Studies 95/05	ABB_SIM 00006794 - ABB_SIM 00006818	A, F, R, H, I
PTX-0269						Final Study Reports for Clinical Studies 95/06	ABB_SIM 00007032 - ABB_SIM 00007083	A, F, R, H, I
PTX-0270						Human Pharmacokinetics and Bioavailability; NDA 20-381, Volume 3.17, 95/06	ABB_SIM 00007414 - ABB_SIM 00007715	A, F, R, H, I
PTX-0271						Clinical Study Report 95/07 Human Pharmacokinetics and Bioavailability; NDA 20-381 Volume 3.18	ABB_SIM 00007716 - ABB_SIM 00008034	A, F, R, H, I
PTX-0272						Clinical Study Report 95/07; NDA 20-381 Vol. 3.19	ABB_SIM 00008035 – ABB_SIM 00008276	A, F, R, H, I
PTX-0273						Kos Pharmaceuticals, Inc., NDA 20-381, Niaspan Controlled-Release Tablets, Human Pharmacokinetics and Bioavailability, Volume 3.20	ABB_SIM 00008277 - ABB_SIM 00008488	A, F, R, H, I
PTX-0274						Kos Pharmaceuticals, Inc., NDA 20-381, Niaspan Controlled-Release Tablets, Human Pharmacokinetics and Bioavailability, Volume 3.22	ABB_SIM 00008815 - ABB_SIM 00009065	A, F, R, H, I
PTX-0276						Kos Pharmaceuticals, Inc., NDA 20-381, Niaspan Controlled-Release Tablets, Human Pharmacokinetics and Bioavailability, Volume 3.26	ABB_SIM 00010044 - ABB_SIM 00010344	A, F, R, H, I

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PTX-0277						NDA 20-381 Clinical Section	ABB_SIM 00010564 - ABB_SIM 00010782	A, F, R, H, I
PTX-0278						Clinical Study Report 91/04; NDA 20-381, Volume 3.30	ABB_SIM 00010783 - ABB_SIM 00011242	A, F, R, H, I
PTX-0279						Clinical Study Report 91/04; NDA 20-381, Volume 3.31	ABB_SIM 00011243 - ABB_SIM 00011651	A, F, R, H, I
PTX-0280						Clinical Study Report 91/04; NDA 20-381, Volume 3.32	ABB_SIM 00011652 - ABB_SIM 00011787	A, F, R, H, I
PTX-0282						Clinical Study Report 91/04; NDA 20-381, Volume 3.34	ABB_SIM 00012143 - ABB_SIM 00012614	A, F, R, H, I
PTX-0283						Clinical Study Report 91/04; NDA 20-381, Volume 3.35	ABB_SIM 00012615 - ABB_SIM 00012997	A, F, R, H, I
PTX-0284						Clinical Study Report 91/04; NDA 20-381, Volume 3.36	ABB_SIM 00012998 - ABB_SIM 00013399	A, F, R, H, I
PTX-0285						Clinical Study Report 91/04; NDA 20-381, Volume 3.37	ABB_SIM 00013400 - ABB_SIM 00013817	A, F, R, H, I
PTX-0286						Clinical Study Report 91/04; NDA 20-381, Volume 3.38	ABB_SIM 00013818 - ABB_SIM 00014063	A, F, R, H, I
PTX-0287						Clinical Study Report 91/04; NDA 20-381, Volume 3.39	ABB_SIM 00014064 - ABB_SIM 00014201	A, F, R, H, I
PTX-0290						Clinical Study Report 91/05; NDA 20-381, Volume 3.42	ABB_SIM 00014696 - ABB_SIM 00015143	A, F, R, H, I
PTX-0292						Clinical Study Report 91/05; NDA 20-381, Volume 3.44	ABB_SIM 00015418 - ABB_SIM 00015632	A, F, R, H, I
PTX-0293						Clinical Study Report 91/05; NDA 20-381, Volume 3.45	ABB_SIM 00015633 - ABB_SIM 00015945	A, F, R, H, I
PTX-0294						Clinical Study Report 91/05; NDA 20-381, Volume 3.46	ABB_SIM 00015946 - ABB_SIM 00016191	A, F, R, H, I
PTX-0295						Clinical Study Report 91/05; NDA 20-381, Volume 3.47	ABB_SIM 00016192 - ABB_SIM 00016462	A, F, R, H, I
PTX-0296						Clinical Study Report 91/05; NDA 20-381, Volume 3.48	ABB_SIM 00016463 - ABB_SIM 00016703	A, F, R, H, I
PTX-0297						Clinical Study Report 91/15; NDA 20-381, Volume 3.49	ABB_SIM 00016704 - ABB_SIM 00016859	A, F, R, H, I
PTX-0301						NDA 20-381, Vol. 3.53, Data Listings - Appendix G for 91/15 (5.1 Series - 5.2 Series)	ABB_SIM 00018097 - ABB_SIM 00018475	A, F, R, H, I
PTX-0302						NDA 20-381, Vol. 3.54, Data Listings - Appendix G for 91/15 (5.3 Series - 10.1 Series)	ABB_SIM 00018476 - ABB_SIM 00018893	A, F, R, H, I

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PTX-0303						NDA 20-381, Vol. 3.55, Data Listings - Appendix G for 91/15 (11.0 Series - 14.0 Series)	ABB_SIM 00018894 - ABB_SIM 00019160	A, F, R, H, I
PTX-0305						NDA 20-381, Vol. 3.57	ABB_SIM 00019637 - ABB_SIM 00019994	A, F, R, H, I
PTX-0306						NDA 20-381, Vol. 3.58	ABB_SIM 00019995 - ABB_SIM 00020340	A, F, R, H, I
PTX-0308						Clinical Study Report 91/09; NDA 20-381, Volume 3.59	ABB_SIM 00020341 - ABB_SIM 00020683	A, F, R, H, I
PTX-0309						Clinical Study Report 91/09; NDA 20-381, Volume 3.60	ABB_SIM 00020684 - ABB_SIM 00021142	A, F, R, H, I
PTX-0310						Clinical Study Report 91/09; NDA 20-381, Volume 3.61	ABB_SIM 00021143 - ABB_SIM 00021465	A, F, R, H, I
PTX-0311						Clinical Study Report 91/09; NDA 20-381, Volume 3.62	ABB_SIM 00021466 - ABB_SIM 00021825	A, F, R, H, I
PTX-0312						Clinical Study Report 91/09; NDA 20-381, Volume 3.63	ABB_SIM 00021826 - ABB_SIM 00022233	A, F, R, H, I
PTX-0313						Clinical Study Report 91/09; NDA 20-381, Volume 3.64	ABB_SIM 00022234 - ABB_SIM 00022548	A, F, R, H, I
PTX-0314						Clinical Study Report 91/09; NDA 20-381, Volume 3.65	ABB_SIM 00022549 - ABB_SIM 00022916	A, F, R, H, I
PTX-0315						Clinical Study Report 91/09; NDA 20-381, Volume 3.66	ABB_SIM 00022917 - ABB_SIM 00023142	A, F, R, H, I
PTX-0316						Clinical Study Report 91/09; NDA 20-381, Volume 3.67	ABB_SIM 00023143 - ABB_SIM 00023448	A, F, R, H, I
PTX-0317						Clinical Study Report 91/09; NDA 20-381, Volume 3.68	ABB_SIM 00023449 - ABB_SIM 00023960	A, F, R, H, I
PTX-0318						Clinical Study Report 91/09; NDA 20-381, Volume 3.69	ABB_SIM 00023961 - ABB_SIM 00024353	A, F, R, H, I
PTX-0319						Clinical Study Report 91/09; NDA 20-381, Volume 3.70	ABB_SIM 00024354 - ABB_SIM 00024793	A, F, R, H, I
PTX-0320						Clinical Study Report 91/03; NDA 20-381, Volume 3.71	ABB_SIM 00024794 - ABB_SIM 00024890	A, F, R, H, I
PTX-0323						Kos Pharmaceuticals, Inc. NDA 30-281, Volume 3.74	ABB_SIM 00025706 - ABB_SIM 00026095	A, F, R, H, I
PTX-0325						From IND Annual Report, Product Name: Niaspan 1000 mg Tablet, 11/22/93	ABB_SIM 00037758 - ABB_SIM 00037768	A, F, R, H, I
PTX-0326						Niaspan (Sustained-Release Niacin Tablets) Amendment to Pending NDA 20-381	ABB_SIM 00038478	A, F, R, H, I
PTX-0327						Department of Health and Human Services Application To Market A New Drug for Human Use Or An Antibiotic Drug For Human Use	ABB_SIM 00038495 - ABB_SIM 00038678	A, F, R, H, I

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PTX-0328						Niaspan Sustained-Release Tablets NDA 20-381 Volume 2.3	ABB_SIM 00039069 - ABB_SIM 00039388	A, F, R, H, I
PTX-0330						Clinical Study Report 89/04 Appendices; NDA 20-381, Volume Number 2.15	ABB_SIM 00042171 - ABB_SIM 00042547	A, F, R, H, I
PTX-0332						Clinical Study Report 91/04; NDA 20-381, Volume Number 2.17	ABB_SIM 00042746 - ABB_SIM 00043147	A, F, R, H, I
PTX-0333						Clinical Study Report 91/04; NDA 20-381, Volume Number 2.18	ABB_SIM 00043148 - ABB_SIM 00043605	A, F, R, H, I
PTX-0334						Clinical Study Report 91/04; NDA 20-381, Volume Number 2.19	ABB_SIM 00043606 - ABB_SIM 00043879	A, F, R, H, I
PTX-0335						Clinical Study Report 91/04; NDA 20-381, Volume Number 2.20	ABB_SIM 00043880 - ABB_SIM 00044278	A, F, R, H, I
PTX-0336						Clinical Study Report 91/04; NDA 20-381, Volume Number 2.21	ABB_SIM 00044279 - ABB_SIM 00044695	A, F, R, H, I
PTX-0337						Clinical Study Report 91/04; NDA 20-381, Volume Number 2.22	ABB_SIM 00044696 - ABB_SIM 00044756	A, F, R, H, I
PTX-0339						Clinical Study Report 91/05; NDA 20-381, Volume Number 2.24	ABB_SIM 00045137 - ABB_SIM 00045473	A, F, R, H, I
PTX-0340						Clinical Study Report 91/05; NDA 20-381, Volume Number 2.25	ABB_SIM 00045474 - ABB_SIM 00045493	A, F, R, H, I
PTX-0341						Clinical Study Report 91/05; NDA 20-381, Volume Number 2.26	ABB_SIM 00045769 - ABB_SIM 00046647	A, F, R, H, I
PTX-0342						Clinical Study Report 91/05; NDA 20-381, Volume Number 2.29	ABB_SIM 00046648 - ABB_SIM 00046703	A, F, R, H, I
PTX-0344						The Comparative Bioavailability of 500mg and 750mg Tablet Strengths of Niaspan, Protocol No. 94/09 Final Report, dated 11/22/1995	ABB_SIM 00065294 - ABB_SIM 00065393	A, F, R, H, I
PTX-0345						Kos Clinical Study 94/09 Synopsis, March 31, 1995	ABB_SIM 00065394 - ABB_SIM 00065446	A, F, R, H, I
PTX-0346						Protocol Number 95/05 Final Report, August 23, 1996	ABB_SIM 00065569 - ABB_SIM 00065625	A, F, R, H, I
PTX-0347						The Comparative Bioavailability of Niaspan Tablets from Three Manufacturing Lots, Protocol No. 95/06, Final Report, March 11, 1996	ABB_SIM 00065626 - ABB_SIM 00065695	A, F, R, H, I
PTX-0348						The Comparative Bioavailability of Three Niaspan Batches Manufactured at Two Different Sites, Protocol No. 95/07, Final Report, March 20, 1996	ABB_SIM 00065696 - ABB_SIM 00065762	A, F, R, H, I
PTX-0349						Niaspan Sustained-Release Tablets Final Report, Protocol 91/05, Revision 1	ABB_SIM 00071699 - ABB_SIM 00071729	A, F, R, H, I

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PTX NO.	DTX NO.	JTX NO.	DATE OFFERED	MARKED	ADMITTED	DESCRIPTION OF EXHIBITS	BATES NUMBER	OBJECTIONS
PTX-0350						Study 89/04, A Single-Blind Placebo Controlled Pilot Study Comparing the Effect of Once-A-Day Versus Twice-A-Day Dosing of Niaspan™ on Serum Lipids, Final Report, Kos Pharmaceuticals, Inc., August 1991	ABB_SIM 00072801 - ABB_SIM 00073005	A, F, R, H, I
PTX-0351						Niacin ER/Simvastatin Tablets, Kos Life Sciences, Inc., 2.3.P.2 Pharmaceutical Development	ABB_SIM 00076631 - ABB_SIM 00076639	A, F, R, H, I
PTX-0352						Kos 2.5 Clinical Overview, CTD Clinical Summary	ABB_SIM 00076775 - ABB_SIM 00076830	A, F, R, H, I, S
PTX-0354						Niacin ER/Simvastatin Tablets, Kos Life Sciences, Inc., Clinical Study Report: 019-03-04 CP, 12.1 Study Information	ABB_SIM 00081395 - ABB_SIM 00081491	A, F, R, H, I
PTX-0357						The Comparative Bioequivalence of Two Niaspan 1000 mg Batches Manufactured at Two Different Sites Representing Two Different Batches Sizes, Study Number 97/05, Final Report, May 15, 1998	ABB_SIM 00255955 - ABB_SIM 00256361	A, F, R, H, I
PTX-0358						Niacin extended-release/simvastatin, 2.5 Clinical Overview, R&D/09/1034	ABB_SIM 00296250 - ABB_SIM 00296263	A, F, R, H, I
PTX-0359						2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods	ABB_SIM 00296265 - ABB_SIM 00296339	H
PTX-0362						Protocol for Kos Study No. 89/04	ABB_SIM 00526932 - ABB_SIM 00526956	A, F, R, H, I
PTX-0369						A Pilot Efficacy Study of a Once-A-Day Sustained-Release Niacin Formulation (Niaspan) in the Treatment of Primary Type IIa Hyperlipidemia, Protocol No. 91/02, Jan. 31, 1991	ABB_SIM 00529701- ABB_SIM 00529750	H
PTX-0371						A Double-Blind Placebo Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan (sustained release niacin) in Patients with Primary Hyperlipoproteinemia, Protocol No. 91/04	ABB_SIM 00529791 - ABB_SIM 00529850	H
PTX-0382						Kos Pharmaceuticals Protocol # 96/02 Final Report, May 6, 1997	ABB_SIM 00542158 - ABB_SIM 00542171	A, F, R, H, I
PTX-0383						Kos Pharmaceuticals Protocol # 96/02 Final Report, May 6, 1997	ABB_SIM 00562153 - ABB_SIM 00564782	A, F, R, H, I
PTX-0385						Center for Drug Evaluation and Research Summary Review for Application No. NDA 22-078 (Feb. 17, 2008), at 3-4, available at http://www.accessdata.fda.gov/drugsatfda_docs/nda/2008/022078s000_SumR.pdf.		A, F, R, H, I, S
PTX-0386						Final Study Reports for Clinical Studies 96/02, May 6, 1997	ABB_S2_00230786 - ABB_S2_00230823	A, F, R, H, I

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LABELS								
PTX-0387						Keenan Rep. Ex 76, Highlights of Prescribing Information for Simcor		H
PTX-0388						Keenan Rep. Ex 78, Advicor - niacin and lovastatin tablet, extended release		H, I
PTX-0389						SIMCOR - simvastatin and niacin tablet, film coated, extended release, Abbott Laboratories	ABB_SIM 00733732 - ABB_SIM 00733762	A, F, R, H, I
PTX-0390						Lipitor Label, Warnings and Precautions	ABB_SIM 01262681 - ABB_SIM 01262703	A, F, R, H, I
PTX-0394						Mevacor Label		A, F, R, H, I
PTX-0395						Zocor (simvastatin) Tablet Label		A, F, R, H, I
PTX-0396						Lipitor Label		A, F, R, H, I
DEFENDANTS' DOCUMENTS								
PTX-0399						Specification and Analytical Report Summary, Purified Water USP Results - STM RM-2014 - Microbiology, August 16, 2010	OCA021868 - OCA021879	F
PTX-0400						3.2.P.5.2 Analytical Procedures for Niacin Extended-release and Simvastatin Tablets, ANDA No. 20-0601	OCA021887 - OCA021888	F
PTX-0401						Watson ANDA, Module 1.12.15 Request for In Vivo Bioequivalence Waiver	WT0016178 - WT0016181	F
PTX-0407						Withdrawn (Teva document)		
PTX-0408						Withdrawn (Teva document)		
PTX-0409						Withdrawn (Teva document)		
PTX-0410						Withdrawn (Teva document)		
PTX-0411						Withdrawn (Teva document)		
PTX-0412						Withdrawn (Teva document)		
PTX-0413						Withdrawn (Teva document)		
PTX-0414						Withdrawn (Teva document)		
PTX-0415						Withdrawn (Teva document)		
PTX-0416						Email dated May 19, 2008 from N. Clark to A. Boyer re: Fw: Generic - May 2008 Final Forecast File	WT0017176 - WT017361	F, R, H, C, P
PTX-0417						Email dated February 19, 2008 from F. Adadevoh re: Healthcare News 2/19/08	WT0024971 - WT0024978	F, R, H, C, P
PTX-0418						Email dated March 25, 2008 from N. Clark to T. McLean re: Revised Forecast	WT0024986 - WT0025048	F, R, H, C, P
PTX-0419						Email dated September 25, 2007 from A. Tagger to S. Goodman re Marketing Action Item Meeting	WT0025366 - WT0025373	F, R, H, C, P
PTX-0420						Email dated June 9, 2009 from T. McLean, et al. to M. Udan, et al. re 3yr forecast for new products	WT0025631 - WT0025743	F, R, H, C, P

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PTX-0421						Email dated May 5, 2010 from Corporate Communications re: Watson Issues Press Release - Confirms SIMCOR® Patent Challenge; Paragraph IV Litigation Underway	WT0026578	F, R, H, C, P
PTX-0422						Email dated December 7, 2009 from C. Miller to A. Power et al. re: Portfolio Material	WT0026617 - WT0026623	F, R, H, C, P
PTX-0423						Email dated March 3, 2010 from K. Gallicano to J. Vaughn et al. re Niacin ER / Simvastatin follow-up	WT0061424 - WT0061427	F, R, H, C, P
PTX-0424						Email dated August 5, 2010 from M. Joshi to L. Borges, et al. re: 500/40 mg simvsatin assay 3932R0005 - Support	WT0173927 - WT0173929	F, R, H, C, P
PTX-0425						Watson Pharmaceuticals Inc. 10-K Annual Report pursuant to section 13 and 15(d) filed on February 22, 2011 for Period December 31, 2010		F, R, H, C, P
PTX-0426						Spreadsheet, Boyer Ex. P-95	WT0024960 - WT0024963	F, R, H, C, P
PTX-0427						R&D Project Approval Form (RPAF) for Niacin ER/Simvastatin 500/20, 750/20, 1000/20mg	WT0026951 - WT0026952	F, R, H, C, P
PTX-0428						R&D Project Approval Form (RPAF) for Niacin ER/Simvastatin 500/20, 750/20, 1000/20mg	WT0179536 - WT0179539	F, R, H, C, P
PTX-0429						R&D Project Approval Form (RPAF) for Niacin	WT0179540 - WT0179543	F, R, H, C, P
PTX-0430						Spreadsheet for API Test Chemicals	WT0179544 - WT0179559	F, R, H, C, P
PTX-0431						R&D Project Approval Form (RPAF) for Niacin ER/Simvastatin 500/20, 750/20, 1000/20mg, 500/40mg, 1000/40mg	WT0179560 - WT0179565	F, R, H, C, P
PTX-0432						R&D Project Approval Form (RPAF) for Niacin ER/Simvastatin 500/20, 750/20, 1000/20mg, 500/40mg, 1000/40mg	WT0179566 - WT0179571	F, R, H, C, P
PTX-0433						R&D Project Approval Form (RPAF) for Niacin ER/Simvastatin 500/20, 750/20, 1000/20mg	WT0179572 - WT0179575	F, R, H, C, P
PTX-0434						Spreadsheet for API Test Chemicals	WT0179576 - WT0179591	F, R, H, C, P
PTX-0435						Spreadsheet for API Test Chemicals	WT0179592 - WT0179602	F, R, H, C, P
PTX-0436						R&D Project Approval Form (RPAF) for Niacin ER/Simvastatin 500/20, 750/20, 1000/20mg	WT0179603 - WT0179608	F, R, H, C, P
PTX-0437						Spreadsheet for API Test Chemicals	WT0179609 - WT0179624	F, R, H, C, P
PTX-0438						Spreadsheet for API Test Chemicals	WT0179625 - WT0179635	F, R, H, C, P
PTX-0439						R&D Project Approval Form (RPAF) for Niacin ER/Simvastatin 500/20, 750/20, 1000/20mg	WT0179636 - WT0179641	F, R, H, C, P
PTX-0440						Spreadsheet for API Test Chemicals	WT0179642 - WT0179657	F, R, H, C, P

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PTX-0441						Spreadsheet for API Test Chemicals	WT0179658 - WT0179668	F, R, H, C, P
PTX-0442						Withdrawn (Teva document)		
SALES/MARKETING/LICENSING								
PTX-0448						Withdrawn		
PTX-0449						Withdrawn		
PTX-0450						Roth Capital Partners Company Report/Equity Research for Kos Pharmaceuticals, October 19, 2006	ABB_S2_00348778 - ABB_S2_00348810	A, F, R, H, I
PTX-0452						Offer to Purchase For Cash All Outstanding Shares of Common Stock of Kos Pharmaceuticals, Inc. by Abbott Laboratories, November 14, 2006	ABB_SIM 00571685 - ABB_SIM 00571786	A, F, R, H, I
PTX-0453						Press release dated July 18, 2008, "Teva to Acquire Barr"	ABB_SIM 00875409 - ABB_SIM00875413	A, F, R, H, I
PTX-0454						Amendment to License Agreement between Kos Pharms., Inc. and Oryx Pharms., Inc., September 29, 2004	ABB_SIM 00937440 - ABB_SIM 00937442	A, F, R, H, I
PTX-0455						Patent Purchase and Assignment Agreement dated January 9, 2002 between Upsher-Smith and Kos	ABB_S2_00149236 - ABB_S2_0001492661	A, F, R, H, I
PTX-0456						United States Patent Assignment dated January 9, 2002 between Upsher-Smith and Kos	ABB_S2_00149327 - ABB_S2_00149329	
PTX-0457						Withdrawn		
PTX-0458						Withdrawn		
PTX-0461						Think Higher HDL-C Think Niaspan	ABB_S2_00568267	A, F, R, H
PTX-0462						Withdrawn		
PTX-0465						Development and License Agreement dated August 18, 2003 between Kos and Oryx	ABB_S2_00855638 - ABB_S2_00855673	A, F, R, H, I
PTX-0466						Withdrawn		
PTX-0467						Withdrawn		
PTX-0469						Aggressive Targets Demand Comprehensive Lipid Management	ABB_SIM 00577624 - ABB_SIM 00577641	A, F, R, H
PTX-0478						http://www.drugs.com/top200.html	ABB_SIM 01262674 - ABB_SIM 01262680	A, F, R, H
PTX-0479						http://www.drugs.com/top200_units.html	ABB_SIM 01262667 - ABB_SIM 01262673	A, F, R, H
PTX-0480						2008 Update Net Sales - Full Year	ABB_S2_00891956	A, F, R, H
PTX-0483						Dyslipidemia TRx and Market Share (Exhibit 110 to 06/17/2010 Deposition of Medgar Williams)	ABB_SIM 00569519 - ABB_SIM 00569530	A, F, R, H, I
PTX-0484						IMS Summary Data - Total Prescription Information for 7/2004 - 6/1/2010	ABB_SIM 00573336 - ABB_SIM 00573339	A, F, R, H, I
PTX-0486						Spreadsheet re: 2007 LRP Dyslipidemia Franchise, Revised Kos LRP vs. Deal Model Reconciliation	ABB_SIM 00687296 - ABB_SIM 00687352	A, F, R, H, I

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PTX-0499						Slo-Niacin Ad		A, F, R, H, NP, I
PTX-0500						Endur-Acin 500mg		A, F, R, H, NP, I
COURT DOCUMENTS								
PTX-0502						Report and Recommendation Regarding Claim Construction, June 18, 2010. Abbott Labs. et al. v. Lupin Limited et al., Civ. No. 09-152-JJF-LPS (D. Del.)		R, H, C, P
PTX-0503						Order Correcting U.S. Patent No. 7,011,848, May 31, 2011. Abbott Labs. et al. v. Lupin Limited et al., Civ. No. 09-152-JJF-LPS (D. Del.)		R, H, C, P
EXPERT MATERIALS								
PTX-0504						Curriculum Vitae of Dr. Michael Bottorff		A, F, R, H
PTX-0505						Curriculum Vitae of Dr. Frank Sacks		A, F, R, H
PTX-0506						Curriculum Vitae of Daniel C. Smith, Ph.D., September 19, 2011		A, F, R, H
PTX-0507						Curriculum Vitae of Robert O. Williams III		A, F, R, H
PTX-0508						Exhibit C (Total Prescriptions Chart) to Expert Report of Daniel C. Smith, Ph.D., September 19, 2011		A, F, R, H
PTX-0509						Exhibit D (Sales Dollars Chart) to Expert Report of Daniel C. Smith, Ph.D., September 19, 2011		A, F, R, H
PTX-0510						List of Materials Considered by Robert O. Williams III for Opening Expert Report to Teva, August 19, 2011		A, F, R, H
PTX-0511						List of Materials Considered by Robert O. Williams III for Opening Expert Report to Watson, August 19, 2011		A, F, R, H
PTX-0512						List of Materials Considered by Robert O. Williams III for Rebuttal Expert Report to Teva, September 19, 2011		A, F, R, H
PTX-0513						List of Materials Considered by Robert O. Williams III for Rebuttal Expert Report to Watson, September 19, 2011		A, F, R, H
PTX-0514						List of Materials Considered by Daniel C. Smith, Ph.D. for Expert Report, September 19, 2011		A, F, R, H
PTX-0515						List of Materials Considered by Dr. Frank Sacks for Rebuttal Expert Report, September 19, 2011		A, F, R, H
PTX-0516						List of Materials Considered by Dr. Frank Sacks for Supplemental Rebuttal Expert Report, October 14, 2011		A, F, R, H

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PTX-0517						List of Materials Considered by Michael B. Bottorff, Pharm.D. for Opening Expert Report to Teva, August 19, 2011		A, F, R, H
PTX-0518						List of Materials Considered by Michael B. Bottorff, Pharm.D. for Opening Expert Report to Watson, August 19, 2011		A, F, R, H
PTX-0519						Amended List of Materials Considered by Michael B. Bottorff, Pharm.D. for Opening Expert Report to Teva, August 19, 2011		A, F, R, H
PTX-0520						Amended List of Materials Considered by Michael B. Bottorff, Pharm.D. for Opening Expert Report to Watson, August 19, 2011		A, F, R, H
PTX-0521						List of Materials Considered by Michael B. Bottorff, Pharm.D. for Rebuttal Expert Report, September 19, 2011		A, F, R, H
PTX-0522						List of Materials Considered by Michael B. Bottorff, Pharm.D. for Supplemental Rebuttal Expert Report, October 14, 2011		A, F, R, H
PTX-0523						Exhibit 2 to Michael B. Bottorff, Pharm.D. Opening Expert Report to Teva, August 19, 2011		A, F, R, H
PTX-0524						Exhibit 3 to Michael B. Bottorff, Pharm.D. Opening Expert Report to Teva, August 19, 2011		A, F, R, H
PTX-0525						Exhibit 4 to Michael B. Bottorff, Pharm.D. Opening Expert Report to Teva, August 19, 2011		A, F, R, H
PTX-0526						Exhibit 5 to Michael B. Bottorff, Pharm.D. Opening Expert Report to Teva, August 19, 2011		A, F, R, H
PTX-0527						Exhibit 6 to Michael B. Bottorff, Pharm.D. Opening Expert Report to Teva, August 19, 2011		A, F, R, H
PTX-0528						Exhibit 7 to Michael B. Bottorff, Pharm.D. Opening Expert Report to Teva, August 19, 2011		A, F, R, H
PTX-0529						Exhibit 2 to Michael B. Bottorff, Pharm.D. Opening Expert Report to Watson, August 19, 2011		A, F, R, H
PTX-0530						Exhibit 3 to Michael B. Bottorff, Pharm.D. Opening Expert Report to Watson, August 19, 2011		A, F, R, H
PTX-0531						Exhibit 4 to Michael B. Bottorff, Pharm.D. Opening Expert Report to Watson, August 19, 2011		A, F, R, H
PTX-0532						Exhibit 5 to Michael B. Bottorff, Pharm.D. Opening Expert Report to Watson, August 19, 2011		A, F, R, H

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PTX-0533						Exhibit 6 to Michael B. Bottorff, Pharm.D. Opening Expert Report to Watson, August 19, 2011		A, F, R, H
PTX-0534						Exhibit 7 to Michael B. Bottorff, Pharm.D. Opening Expert Report to Watson, August 19, 2011		A, F, R, H
PTX-0535						Exhibit 3 to Robert O. Williams III Opening Expert Report to Teva, August 19, 2011		A, F, R, H
PTX-0536						Exhibit 4 to Robert O. Williams III Opening Expert Report to Teva, August 19, 2011		A, F, R, H
PTX-0537						Exhibit 3 to Robert O. Williams III Opening Expert Report to Watson, August 19, 2011		A, F, R, H
PTX-0538						Exhibit 4 to Robert O. Williams III Opening Expert Report to Watson, August 19, 2011		A, F, R, H
KOS DOCUMENTS								
PTX-0539						Development Activities Overview	ABB_S2_00044657 - ABB_S2_00044659	A, F, R, H, C, S
PTX-0540						Niaspan Production vs. Plan Finished Bulk Tablets as of October 4, 1999	ABB_S2_00076033	A, F, R, H, C, S
PTX-0541						Efforts to establish an IVIVC for Niaspan	ABB_S2_00076768 - ABB_S2_00076772	A, F, R, H, C, S
PTX-0542						Graph 6.12.1A HDL2 Cholesterol to HDL3 Cholesterol Ratio Mean Percent Change From Baseline Efficacy-Analyzable Population 1	ABB_S2_00121452 - ABB_S2_00121453	A, F, R, H, C, S, I, ID
PTX-0543						Withdrawn		
PTX-0548						Medline Search on Niacin 1987 - 1989	ABB_SIM 00558800 - ABB_SIM 00559396	A, F, R, H, C, S, I
PTX-0549						Invention Disclosure by E. Cefali and M. Adams, April 22, 1996	ABB_SIM 00566745 - ABB_SIM 00566749	A, F, R, H, C, I
PTX-0551						Kos Pharmaceuticals Form 10-K (2001)	ABB_SIM 00945482 - ABB_SIM 00945536	A, F, R, H
ASSIGNMENT DOCUMENTS								
PTX-0552						Patent Assignment History, August 22, 1989		A, F, R, H, C, S, I
PTX-0553						Licensing Agreement between Abbott Respiratory and Abbott Laboratories, March 5, 2009	ABB_SIM 00571787 - ABB_SIM 00571791	A, F, R, H, I
PTX-0554						Amendment to Licensing Agreement between Abbott Respiratory and Abbott Laboratories, January 22, 2010	ABB_SIM 00571792	A, F, R, H, I

EXHIBIT N

EXHIBIT N

DEFENDANTS' EXHIBIT LIST WITH PLAINTIFFS' OBJECTIONS

Defendants hereby submit their exhibit list and Plaintiffs' objections thereto. Plaintiffs used the following abbreviations for objections to proposed exhibits:

Abbreviation	Objection
106	Incomplete Document (FRE 106)
402	Irrelevant and/or Immaterial (FRE 402)
403	Cumulative, Duplicative, Wasteful or Undue Delay (FRE 403)
408	Compromise or Offer to Compromise (FRE 408)
802	Hearsay (FRE 802)
901	Authenticity (FRE 901)
1002	Best Evidence Rule Prohibits Introduction (FRE 1002)
D	Demonstrative/Should Not Be Admitted Into Evidence

EXHIBIT N

Defendants' Joint Trial Exhibit List and Plaintiffs' Objections**							
***Abbott Laboratories, et al. v. Teva Pharmaceuticals USA, Inc., et al.*,** **Civil Action No. 10-cv-0057-SLR-MPT (Consolidated) (D.DE.)**							
** Plaintiffs offer the following objections subject to the key and general objections contained in the December 7, 2011 and December 12, 2011 letters from Mr. Stern to Messrs. Werner and Sorenson							
DTX No.	**PTX No.**	**JTX No.**	**Depo Exh No(s).**	**Production Range**	**Date**	**Description**	**Objection(s)**
1			SIM-028 (Bova); SIM-334 (Williams)	TV0005540 - TV0005553	06/27/2000	U.S. Patent No. 6,080,428 (Certified)	Lack of foundation for date description
2				TV0005554 - TV0005735	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 1 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
3				TV0005736 - TV0005904	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 2 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
4				TV0005905 - TV0006076	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 3 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
5				TV0006077 - TV0006242	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 4 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
6				TV0006243 - TV0006414	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 5 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
7				TV0006415 - TV0006559	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 6 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
8				TV0006560 - TV0006718	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 7 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
9				TV0006719 - TV0006874	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 8 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
10				TV0006875 - TV0007045	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 9 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
11				TV0007046 - TV0007203	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 10 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
12				TV0007204 - TV0007398	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 11 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)

EXHIBIT N

DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
13				TV0007399 - TV0007577	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 12 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
14				TV0007578 - TV0007733	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 13 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
15				TV0007734 - TV0007911	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 14 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
16				TV0007912 - TV0008077	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 15 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
17				TV0008078 - TV0008246	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 16 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
18				TV0008247 - TV0008431	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 17 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
19				TV0008432 - TV0008613	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 18 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
20				TV0008614 - TV0008780	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 19 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
21				TV0008781 - TV0008935	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 20 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
22				TV0008936 - TV0009117	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 21 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
23				TV0009118 - TV0009323	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 22 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
24				TV0009324 - TV0009509	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 23 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
25				TV0009510 - TV0009661	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 24 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
26				TV0009662 - TV0009843	01/14/1995	File History for U.S. Patent Number 6,080,428 (Part 25 of 25) (Certified)	106, Lack of foundation for date description, 403 (cumulative)

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
27			SIM-013 (Bova); SIM-340 (Williams)	TV0009844 - TV0009861	10/10/2000	U.S. Patent No. 6,129,930 (Certified)	Lack of foundation for date description
28				TV0009862 - TV0010333	03/06/1997	File History for U.S. Patent Number 6,129,930 (Part 1 of 8) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
29				TV0010334 - TV0010848	03/06/1997	File History for U.S. Patent Number 6,129,930 (Part 2 of 8) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
30				TV0010849 - TV0011302	03/06/1997	File History for U.S. Patent Number 6,129,930 (Part 3 of 8) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
31				TV0011303 - TV0011805	03/06/1997	File History for U.S. Patent Number 6,129,930 (Part 4 of 8) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
32				TV0011806 - TV0012266	03/06/1997	File History for U.S. Patent Number 6,129,930 (Part 5 of 8) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
33				TV0012267 - TV0012765	03/06/1997	File History for U.S. Patent Number 6,129,930 (Part 6 of 8) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
34				TV0012766 - TV0013280	03/06/1997	File History for U.S. Patent Number 6,129,930 (Part 7 of 8) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
35				TV0013281 - TV0013705	03/06/1997	File History for U.S. Patent Number 6,129,930 (Part 8 of 8) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
36			SIM-014 (Bova)	TV0013706 - TV0013731	06/18/2002	U.S. Patent No. 6,406,715 (Certified)	Lack of foundation for date description
37				TV0013732 - TV0014040	10/31/1997	File History for U.S. Patent Number 6,406,715 (Part 1 of 2) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
38				TV0014041 - TV0014327	10/31/1997	File History for U.S. Patent Number 6,406,715 (Part 1 of 2) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
39			SIM-027 (Bova)	TV0014328 - TV0014350	10/22/2002	U.S. Patent No. 6,469,035 (Certified)	Lack of foundation for date description
40				TV0014351 - TV0014692	07/31/1997	File History for U.S. Patent Number 6,469,035 (Certified)	106, Lack of foundation for date description, 403 (cumulative)
41			SIM-007 (Bova); SIM-343 (Williams)	TV0014693 - TV0014722	01/13/2004	U.S. Patent No. 6,676,967 (Certified)	Lack of foundation for date description

EXHIBIT N

DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
42				TV0014723 - TV0014955	10/31/1997	File History for U.S. Patent Number 6,676,967 (Part 1 of 2) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
43				TV0014956 - TV0015183	10/31/1997	File History for U.S. Patent Number 6,676,967 (Part 1 of 2) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
44			SIM-008 (Bova); SIM-342 (Williams)	TV0015184 - TV0015211	06/08/2004	U.S. Patent No. 6,746,691 (Certified)	Lack of foundation for date description
45				TV0015212 - TV0015481	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 1 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
46				TV0015482 - TV0015769	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 2 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
47				TV0015770 - TV0016042	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 3 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
48				TV0016043 - TV0016357	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 4 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
49				TV0016358 - TV0016673	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 5 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
50				TV0016674 - TV0016987	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 6 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
51				TV0016988 - TV0017290	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 7 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
52				TV0017291 - TV0017583	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 8 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
53				TV0017584 - TV0017918	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 9 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
54				TV0017919 - TV0018234	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 10 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
55				TV0018235 - TV0018569	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 11 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
56				TV0018570 - TV0018894	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 12 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
57				TV0018895 - TV0019218	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 13 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
58				TV0019219 - TV0019520	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 14 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
59				TV0019521 - TV0019816	10/31/1997	File History for U.S. Patent Number 6,746,691 (Part 15 of 15) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
60			SIM-015 (Bova)	TV0019817 - TV0019847	11/16/2004	U.S. Patent No. 6,818,229 (Certified)	Lack of foundation for date description
61				TV0019848 - TV0019849	10/31/1997	File History for U.S. Patent Number 6,818,229 (Certification page with image of USPTO certified CD-Rom) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
62				TV0019850 - TV0022335	10/31/1997	File History for U.S. Patent Number 6,818,229 (Contents of USPTO certified CD-Rom) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
63			SIM-016 (Bova)	TV0022336 - TV0022348	03/14/2006	U.S. Patent No. 7,011,848 (Certified)	Lack of foundation for date description
64				TV0022349 - TV0022350	12/22/1999	File History for U.S. Patent Number 7,011,848 (Certification page with image of USPTO certified CD-Rom) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
65				TV0022351 - TV0022614	12/22/1999	File History for U.S. Patent Number 7,011,848 (Contents of USPTO certified CD-Rom) (Certified)	106, Lack of foundation for date description, 403 (cumulative)
66			DDX-001 (Blanford)	ABB_SIM00526824 - ABB_SIM00526826	06/26/2003	Kos v. Barr: Notice of Depositions	402
67			DDX-002 (Blanford)	ABB_SIM00526827 - ABB_SIM00526833	06/02/2003	Kos v. Barr: Barr Laboratories, Inc.'s Notice of Deposition Pursuant to Rule 30(b)(6)	402
68			DDX-003 (Blanford)	ABB_SIM00526834 - ABB_SIM00526835		Kos Pharmaceuticals Inc., Organizational Charts (Officers and Direct Management Reports and Sales & Marketing)	
69			DDX-004 (Blanford)	ABB_SIM00526836		Kos Pharmaceuticals Inc., Organizational Chart (Officers)	
70			DDX-005 (Blanford)	ABB_SIM00526837 - ABB_SIM00526839		Kos Pharmaceuticals Inc., Senior Management	
71			DDX-006 (Blanford)	ABB_SIM00526840 - ABB_SIM00527171	03/26/1990	Letter from David J. Bova, Vice President, Kos Pharmaceuticals, Inc., to the Food and Drug Administration with Investigational New Drug Applications (IND's)	403 (cumulative)
72			DDX-007 (Blanford)	ABB_SIM00527172 - ABB_SIM00527176	01/27/1992	Letter from David J. Bova, Vice President, Kos Pharmaceuticals, Inc., to the Food and Drug Administration regarding Investigational New Drug (IND) 34,613	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
73			DDX-008 (Blanford)	ABB_SIM00527177 - ABB_SIM00527181	07/25/1994	Facsimile from Donald Raineri, Pharm.D. to Daniel Bell (with enclosure)	
74			DDX-009 (Blanford)	ABB_SIM00527182 - ABB_SIM00527186	08/28/2002	Regulatory Affairs, Niaspan NDA Correspondence List from 1993 - Present	
75			DDX-010 (Blanford)	ABB_SIM00527187 - ABB_SIM00527396	05/03/1996	Kos Pharmaceuticals, Inc.'s Application to Market a new Drug for Human Use or an Antibiotic Drug for Human Use regarding NDA 20-381	
76			DDX-011 (Blanford)	ABB_SIM00527397 - ABB_SIM00527451	04/23/1996	Kos Pharmaceuticals, Inc., Niaspan™ Controlled-Release Tablets, Clinical Section regarding NDA 20-381	
77			DDX-012 (Blanford)	ABB_SIM00527452 - ABB_SIM00527463		Kos Pharmaceuticals, Inc., Niaspan™ Controlled-Release Tablets, Chemistry, Manufacturing, Controls regarding NDA 20-381	
78			DDX-013 (Blanford)	ABB_SIM00527464 - ABB_SIM00527470	04/09/1996	Internal Memorandum regarding Minutes of Niaspan™ Project Meeting	
79			DDX-014 (Blanford)	ABB_SIM00527471 - ABB_SIM00527472	08/06/1996	Internal Memorandum regarding Nicobid® Contents	
80			DDX-015 (Blanford)	ABB_SIM00527473 - ABB_SIM00527475	05/22/1996	Internal Memorandum regarding The Competitive SR niacin dissolution project	
81			DDX-016 (Blanford)	ABB_SIM00527476 - ABB_SIM00527485	10/11/1996	Kos Pharmaceuticals, Inc., A 500 mg Niacin Comparative Dissolution Study, Report/Study No: PESR960007	
82			DDX-017 (Blanford)	ABB_SIM00527486 - ABB_SIM00527487	06/25/1996	Internal Memorandum regarding NDA 20-381: Questions from Eric Colman, M.D.	
83			DDX-023 (Blanford)	ABB_SIM00527552 - ABB_SIM00527556	11/02/2000	Kos Pharmaceuticals, Inc., Submission of Patent Information Niaspan® (extended-release tablets), Volume 1 of 1	402
84			DDX-024 (Blanford)	ABB_SIM00527557 - ABB_SIM00527561	07/17/2002	Kos Pharmaceuticals, Inc., Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use regarding NDA 20-381, Patient Information Submission Form	402
85			DDX-025 (Blanford)	ABB_SIM00527562 - ABB_SIM00527566	08/06/2002	Letter from Marvin F. Blanford, Vice President of Compliance, Kos Pharmaceuticals, Inc., to the Food and Drug Administration regarding Niaspan™ NDA 20-381, Submission of Corrected Information Regarding Newly Issued Patent (with enclosure)	402
86			DDX-026 (Blanford)	ABB_SIM00527567 - ABB_SIM00527575	09/06/1996	Internal Memorandum regarding Development and Rational for Once-A-Day at Bedtime Dosing for Niaspan®	403 (cumulative)
87			DDX-027 (McGovern)	ABB_SIM00527576 - ABB_SIM00527582	08/21/2003	Kos v. Barr: Barr Laboratories, Inc.'s First Amended Notice of Deposition Pursuant to Rule 30(b)(6)	402
88			DDX-028 (McGovern)	ABB_SIM00527583 - ABB_SIM00527585	08/21/2003	Kos v. Barr: Barr's First Amended Notice of Deposition for Mark McGovern	402
89			DDX-029 (McGovern)	ABB_SIM00527586 - ABB_SIM00527600	03/07/2003	Kos v. Barr: Barr Laboratories, Inc.'s First Set of Document Requests (Nos. 1-81) in Kos III to Plaintiff	402
90			DDX-030 (McGovern)	ABB_SIM00527601 - ABB_SIM00527605	04/02/1997	Kos Pharmaceuticals, Inc., Contract Clinical Monitor Newsletter	402
91			DDX-031 (McGovern)	ABB_SIM00527606 - ABB_SIM00527608	02/24/2000	Facsimile from Deyanira Taborda to MSC, Kathy Schoff regarding ACC press related materials (with enclosure)	402

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
92			DDX-032 (McGovern)	ABB_SIM00527609 - ABB_SIM00527623	04/09/2001	Kos Pharmaceuticals, Inc., Organizational Charts	403 (cumulative)
93			DDX-033 (McGovern)	ABB_SIM00527624 - ABB_SIM00527636	1/15/2002	Kos Pharmaceuticals, Inc., Organizational Charts	403 (cumulative)
94			DDX-034 (McGovern)	ABB_SIM00527637 - ABB_SIM00527640		Corporate Management Committee' minutes with handwritten notes	901, 402
95			DDX-035 (McGovern)	ABB_SIM00527641	11/15/1999	Correspondence from Mark McGovern regarding Slo-Niacin information sheet	802
96			DDX-036 (Messick)	ABB_SIM00527642- ABB_SIM00527644	08/25/2003	Kos v. Barr: Barr's First Amended Notice of Deposition for Karen Messick	402
97			DDX-037 (Messick)	ABB_SIM00527645 - ABB_SIM00527651	08/25/2003	Kos v. Barr: Barr Laboratories, Inc.'s Second Amended Notice of Deposition Pursuant to Rule 30(b)(6)	402
98			DDX-038 (Messick)	ABB_SIM00527652 - ABB_SIM00527654	09/18/2002	Correspondence from Marijke Adams to Sue Balandis enclosing Memorandum regarding Niaspan PK/metabolism manuscript preparation and publication (with enclosure)	402
99			DDX-039 (Messick)	ABB_SIM00527655 - ABB_SIM00527657	10/07/2002	Correspondence from Marijke Adams regarding Niaspan PK manuscript update (with enclosure)	402
100			DDX-040 (Messick); SIM-376 (Sacks)	ABB_SIM00527658 - ABB_SIM00527690	10/25/1993	Patent Application Serial No. M/124392, U.S. Department of Commerce Patent and Trademark Office, Fee Record Sheet	106, 403 (cumulative)
101			DDX-041 (Messick)	ABB_SIM00527691 - ABB_SIM00527695	07/07/1994	USPTO Examiner's Action regarding Serial No. 08/124,392	106, 403 (cumulative)
102			DDX-042 (Messick)	ABB_SIM00527696		USPTO Examiner Interview Summary Record regarding Serial No. 08/124,392	106, 403 (cumulative)
103			DDX-043 (Messick)	ABB_SIM00527697	01/23/1995	USPTO Notice of Abandonment regarding Serial No. 08/124,392	106, 403 (cumulative)
104			DDX-044 (Messick)	ABB_SIM00527698 - ABB_SIM00527729	03/13/1995	Patent Application Serial No. 08/368,378, U.S. Department of Commerce Patent and Trademark Office, Fee Record Sheet	106, 403 (cumulative)
105			DDX-045 (Messick)	ABB_SIM00527730 - ABB_SIM00527731	07/30/1999	Letter from Mukesh Patel, Vice President, Licensing, Kos Pharmaceuticals, Inc., to Barbara Saunders, Associate General Counsel, DuPont Pharmaceuticals Company	
106			DDX-046 (Messick)	ABB_SIM00527732 - ABB_SIM00527759	03/09/1990	Protocol Number 89/04: A Single-Blind Placebo Controlled Pilot Study Comparing the Effect of Once-A-Day Versus Twice-A-Day Dosing of Sustained Release Niacin on Serum Lipids	
107			DDX-047 (Messick)	ABB_SIM00527760 - ABB_SIM00527767	04/14/1995	USPTO Transmittal Sheet and Information Disclosure Statement regarding Serial No. 08/368,378	106, 403 (cumulative)
108			DDX-048 (Messick)	ABB_SIM00527768 - ABB_SIM00527771	06/30/1995	USPTO Examiner's Action regarding Serial No. 08/368,378	106, 403 (cumulative)
109			DDX-049 (Messick)	ABB_SIM00527772 - ABB_SIM00527774	08/17/1995	USPTO Declaration of David J. Bova regarding Serial No. 08/368,378	106, 403 (cumulative)
110			DDX-050 (Messick)	ABB_SIM00527775 - ABB_SIM00527780	08/23/1995	USPTO Response to Examiner's Action dated 06/30/1995 regarding Serial No. 08/368,378	106, 403 (cumulative)
111			DDX-051 (Messick)	ABB_SIM00527781 - ABB_SIM00527795	03/27/1996	USPTO Declaration of David J. Bova regarding Serial No. 08/368,378	106, 403 (cumulative)

EXHIBIT N

DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
112			DDX-052 (Messick)	ABB_SIM00527796	11/22/1996	USPTO Communication from the Examiner regarding Serial No. 08/368,378	106, 403 (cumulative)
113			DDX-053 (Messick)	ABB_SIM00527797 - ABB_SIM00528167	12/17/1996	Kos Pharmaceuticals Inc - KOSP, Form S-1	
114			DDX-054 (Kiritsy)	ABB_SIM00528168 - ABB_SIM00528170	08/25/2003	Kos v. Barr: Barr's First Amended Notice of Deposition for Chris Kiritsy	402
115			DDX-055 (Kiritsy)	ABB_SIM00528171 - ABB_SIM00528177	08/25/2003	Kos v. Barr: Barr Laboratories, Inc.'s Third Amended Notice of Deposition Pursuant to Rule 30(b)(6)	402
116			DDX-056 (Kiritsy)	ABB_SIM00528178 - ABB_SIM00528187	10/08/1996	Kos Pharmaceuticals, Inc., PMSI Audited U.S. Market for Cholesterol Lowering-Prescriptions (For 12 Months Ending July 1996)	
117			DDX-057 (Kiritsy)	ABB_SIM00528188 - ABB_SIM00528220	03/06/1996	Confidential Review of Kos Pharmaceuticals, Inc.	
118			DDX-058 (Kiritsy)	ABB_SIM00528221	02/07/1996	Kos Pharmaceuticals, Inc., Projected Revenue for Niaspan™	
119			DDX-059 (Kiritsy)	ABB_SIM00528222 - ABB_SIM00528228	08/30/1996	Letter from David L. Heatherman to Daniel Bell	
120			DDX-060 (Kiritsy)	ABB_SIM00528229 - ABB_SIM00528234	01/21/1994	Facsimile to David J. Bova regarding Kos Pharmaceuticals, Inc. Confidential Summary of Operations for 1993 (with enclosure)	
121			DDX-061 (Kiritsy)	ABB_SIM00528235 - ABB_SIM00528252	01/30/1997	Kos Pharmaceuticals, Inc., Review for Michael Jaharis	
122			DDX-062 (Kiritsy)	ABB-SIM00528253 - ABB_SIM00528264	02/11/1997	Sales Memorandum: Kos Pharmaceuticals, Inc., 3,500,000 Shares of Common Stock, Initial Public Offering	
123			DDX-063 (Kiritsy)	ABB_SIM00528265 - ABB_SIM00528271	09/24/1997	Facsimile to Chris Kiritsy with enclosure	802
124			DDX-064 (Kiritsy); SUN-007 (McGovern)	ABB_SIM00528272 - ABB_SIM00528306	02/01/1997	Niaspan: 1997 Marketing Plan	Lack of foundation for date description
125			DDX-065 (Kiritsy)	ABB_SIM00528307	06/01/1997	Kos Pharmaceuticals, Inc., Bristol-Myers Squibb	106, 402, Lack of foundation for date description
126			DDX-066 (Kiritsy)	ABB_SIM00528308 - ABB_SIM00528321	09/30/1997	Kos Pharmaceuticals, Inc., Form 10-Q	
127			DDX-067 (Kiritsy)	ABB_SIM00528322 - ABB_SIM00528323	11/13/1997	Press Release, Earnings report hits KOS stock, Business: The Herald (November 13,1997) (on file with Michele Chandler)	802
128			DDX-068 (Kiritsy)	ABB_SIM00528324	11/20/1997	Memorandum regarding Forecast of sales volumes for Niaspan	402
129			DDX-069 (Bell)	ABB_SIM00528325 - ABB_SIM00528327	09/16/2003	Kos v. Barr: Barr's First Amended Notice of Deposition for Daniel Bell	402
130			DDX-070 (Bell)	ABB_SIM00528328 - ABB_SIM00528331	2/2/1988 - 12/22/1990	Dr. Theohardies' handwritten notes	802, 901
131			DDX-071 (Bell)	ABB_SIM00528332	3/8/1989 - 9/20/1993	Timetable for Niaspan® Development	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
132			DDX-072 (Bell); SIM-004 (Bova)	ABB_SIM00528333 - ABB_SIM00528341	09/06/1996	Internal Memorandum regarding Development and Rational for Once-A-Day at Bedtime Dosing for Niaspan®	403 (cumulative)
133			DDX-073 (Bell)	ABB_SIM00528342 - ABB_SIM00528350	03/19/1996	Facsimile to Examiner regarding U.S. Serial No. 08/368,378 with enclosure	106
134			DDX-074 (Bell)	ABB_SIM00528351 - ABB_SIM00528356	11/23/1998	Letter from Daniel M. Bell, President and CEO, Kos Pharmaceuticals, Inc., to Lutz Lingnau, President and CEO, Schering Berlin Inc. with attachments	
135			DDX-075 (Bell)	ABB_SIM00528357 - ABB_SIM00528364	05/27/1993	Memorandum regarding Upsher-Smith Information with enclosures	802
136			DDX-076 (Bell); SIM-026 (Bova)	ABB_SIM00528365 - ABB_SIM00528368	07/01/1993	Internal Memorandum regarding Niaspan™ Studies Post NDA Submission	
137			DDX-077 (Bell)	ABB_SIM00528369 - ABB_SIM00528389	02/23/1994	Memorandum regarding Upsher-Smith Niacin Information with enclosures	802
138			DDX-078 (Bell)	ABB_SIM00528390 - ABB_SIM00528394	08/19/1996	Facsimile to Daniel Bell regarding Wu and Gray article with enclosure	
139			DDX-079 (Bell)	ABB_SIM00528395	11/14/1996	Memorandum regarding Indirect comparison of Niaspan, Slo-niacin, and Enduracin	
140			DDX-080 (Bell)	ABB_SIM00528396 - ABB_SIM00528399	12/16/1996	Facsimile to Daniel Bell regarding Upsher-Smith	802
141			DDX-081 (Bell)	ABB_SIM00528400 - ABB_SIM00528403	01/27/1997	Facsimile to Rod Bell enclosing January 27, 1997 letter from Daniel Bell (Kos Pharmaceuticals, Inc.) to Ian Troup (Upsher-Smith Laboratories, Inc.) with enclosure	408
142			DDX-082 (Bell)	ABB_SIM00528404 - ABB_SIM00528424	02/07/1997	License Agreement between Upsher-Smith Laboratories, Inc. and Kos Pharmaceuticals, Inc.	403 (cumulative)
143			DDX-083 (Bell)	ABB_SIM00528425	2/27/2001	Kos - DuPont Intellectual Property Matters, February 27, 2001 - Miami - mid-day	802
144			DDX-084 (Toth)	ABB_SIM00528426 - ABB_SIM00528428	09/29/2003	Kos v. Barr: Barr's Second Amended Notice of Deposition for George Toth	402
145			DDX-085 (Toth)	ABB_SIM00528429 - ABB_SIM00528434	02/26/1999	USPTO Declaration of George M. Toth regarding Serial No. 08/368,378	106, 403 (cumulative)
146			DDX-086 (Toth); SIM-193 (Toth)	ABB_SIM00528435 - ABB_SIM00528468	10/16/1989 - 11/3/1989	Laboratory Notebook Number 002; Chemist: George M. Toth	
147			DDX-087 (Toth); SIM-195 (Toth)	ABB_SIM00528469 - ABB_SIM00528481	11/01/1989	Facsimile to David Bova regarding Niacin Profile F9303C + D with enclosure	802
148			DDX-088 (Toth)	ABB_SIM00528482 - ABB_SIM00528488	11/17/1989	Facsimile to George Toth with enclosures	
149			DDX-089 (Toth); SIM-011 (Bova)	ABB_SIM00528489 - ABB_SIM00528504	11/28/1989	Facsimile to Roger Cohn, Pat Winfield and George Toth enclosing November 28, 1989 with enclosure	
150			DDX-090 (Toth)	ABB_SIM00528505 - ABB_SIM00528673	2/15/1990 - 4/27/1990	Laboratory Notebook Number 006; Chemist: George M. Toth	
151			DDX-091 (Toth)	ABB_SIM00528674	10/01/1992	Kos Pharmaceuticals, Inc., Organization Chart	403
152			DDX-092 (Toth)	ABB_SIM00528675 - ABB_SIM00529070	4/19/1996 - 7/22/1996	Laboratory Notebook Number 107; Chemist: George Stevens	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
153			DDX-093 (Toth)	ABB_SIM00529071 - ABB_SIM00529072	09/11/1995	Internal Memorandum regarding Niaspan Project	
154			DDX-094 (Toth)	ABB_SIM00529073 - ABB_SIM00529076	07/14/1997	Internal Memorandum regarding F2 Criteria of the Production Lots	
155			DDX-095 (Toth)	ABB_SIM00529077 - ABB_SIM00529082	10/10/1995	Internal Memorandum regarding Minutes of Niaspan™ Project Meeting	
156			DDX-096 (Toth)	ABB_SIM00529083 - ABB_SIM00529088	10/16/1995	Internal Memorandum regarding Minutes of Niaspan™ Project Meeting	403
157			DDX-097 (Toth)	ABB_SIM00829089 - ABB_SIM00529090		Handwritten notes	402, 802, 403 (cumulative)
158			DDX-098 (Toth); SIM-198 (Toth)	ABB_SIM00529091 - ABB_SIM00529096	08/13/1994	Internal Memorandum regarding R&D Project Update	403 (cumulative), 802
159			DDX-099 (Toth)	ABB_SIM00529097	02/11/1992	Letter from George M. Toth, Manager, Quality Control, to Dr. Katsumi Shibata, Professor of Nutrition Sciences, Teikoku Women's University	
160			DDX-100 (O'Neill)	ABB_SIM00565121 - ABB_SIM00565173	07/11/2003	Kos v. Barr: Subpoena to Victoria O'Neill (for documents and testimony)	402
161			DDX-101 (O'Neill)	ABB_SIM00565174 - ABB-SIM00565178	09/05/2003	Kos v. Barr: Subpoena to Upsher-Smith Laboratories, Inc. (for testimony)	402
162			DDX-102 (O'Neill)	ABB_SIM00565179 - ABB_SIM00565189	12/23/1992	Physicians' Desk Reference, 47th edition (1993): excerpts	106
163			DDX-103 (O'Neill)	ABB_SIM00565190 - ABB_SIM00565223	7/10/1987 - 5/19/1988	Laboratory Notebook Number 102; Chemist: Victoria O'Neill	802, 901
164			DDX-104 (O'Neill)	ABB_SIM00565224 - ABB_SIM00565238		Clinical Report, Project No. 901455: Comparative, Randomized, 3-Way Crossover Study of Upsher-Smith 500mg Sustained-Release Niacin Tablets and Rhone-Poulenc Rorer (Nicolar) 500 MG Niacin Tablets in Healthy Adult Males Under Fed and Fasted Conditions	802, 901
165			DDX-105 (O'Neill)	ABB_SIM00565239 - ABB_SIM00565246	7/17/1992	Protocol Synopsis, Project Number 901455: Comparative, Randomized, 3-Way Crossover Study of Upsher-Smith 500mg Sustained-Release Niacin Tablets and Rhone-Poulenc Rorer (Nicolar) 500 MG Niacin Tablets in Healthy Adult Males Under Fed and Fasted Conditions	802, 901
166			DDX-106 (O'Neill)	ABB_SIM00565247 - ABB_SIM00565250		Niacor-SR® (Polygel® Controlled-Release Niacin), Protocol 901455, Summary Report	802, 901
167			DDX-107 (O'Neill)	ABB_SIM00565251 - ABB_SIM00565252	06/01/1993	Letter from Joseph H. Feldhouse, Director, Licensing and Acquisitions, Solvay Pharmaceuticals to Kade Kadrie, Vice President, Sales and Marketing, Upsher-Smith (June 1, 1993)	802, 901
168			DDX-108 (O'Neill)	ABB_SIM00565253	06/01/1993	Letter from Joseph H. Feldhouse, Director, Licensing and Acquisitions, Solvay Pharmaceuticals to Kade Kadrie, Vice President, Sales and Marketing, Upsher-Smith (June 1, 1993) with handwritten notes	802, 901

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
169			DDX-109 (O'Neill)	ABB_SIM00565254 - ABB_SIM00565261	07/09/1993	Letter from Kade Kadrie, Senior Vice President, Sales and Marketing, Upsher-Smith Laboratories, Inc. to Joe Feldhouse, Director of Licensing, Solvay Pharmaceuticals regarding Niacor®-SR (July 9, 1993)	802, 901
170			DDX-111 (O'Neill)	ABB_SIM00565262 - ABB_SIM00565265	05/08/1991	Neuvonen, et al., *The bioavailability of sustained release nicotinic acid formulations,* 32 Br. J. Clin. Pharmacol., pp. 473-476 (1991)	
171			DDX-112 (O'Neill)	ABB_SIM00565266 - ABB_SIM00565268	03/25/1994	Niacor-SR® Literature Review, Teleconference with Solvay, March 25, 2994: A Comparison of the Efficacy and Toxic Effects of Sustained vs. Immediate-Release Niacin in Hypercholesterolemic Patients (JAMA 1994; 274: 672-677);	802, 901, 1002
172			DDX-114 (O'Neill)	ABB_SIM00565275	06/02/1994	Project Team Update regarding Niacor SR Meeting 6/2/94	802, 901, 402
173			DDX-115 (O'Neill)	ABB_SIM00565276 - ABB_SIM00565362	06/29/1992	File History regarding Serial No. 07/905,785 (U.S. Patent No. 5,268,131)	Lack of foundation for date description, 403 (cumulative)
174			DDX-116 (O'Neill)	ABB_SIM00565363 - ABB_SIM00565466	06/11/1990	File History regarding Serial No. 07/536,134 (U.S. Patent No. 5,126,145)	Lack of foundation for date description, 403 (cumulative)
175			DDX-117 (O'Neill)	ABB_SIM00565467 - ABB_SIM00565469	01/27/1997	Letter from Daniel M. Bell, President and CEO, Kos Pharmaceuticals, Inc., to Ian Troup, President and COO, Upsher-Smith Laboratories, Inc. (January 27, 1997) with handwritten notes	403 (cumulative), 408
176			DDX-118 (O'Neill)	ABB_SIM00565470 - ABB_SIM00565489	02/07/1997	License Agreement between Upsher-Smith Laboratories, Inc. and Kos Pharmaceuticals, Inc.	
177			DDX-119 (O'Neill)	ABB_SIM00565490 - ABB_SIM00565491	07/20/2000	Correspondence from Mike Poirier regarding Niacin Notes with enclosure (Niacin ER Meeting Minutes, Discussion of Patent Position (July 14, 2000))	802, 901, 402
178			DDX-120 (O'Neill)	ABB_SIM00565492 - ABB_SIM00565494		Summary of Meeting in Miami with Kos on March 8, 2001	802, 408, 901
179			DDX-121 (O'Neill)	ABB_SIM00565495 - ABB_SIM00565497	03/22/2001	Letter from Ian Troup, President and COO, Upsher-Smith Laboratories, Inc., to Daniel M. Bell, President and CEO, Kos Pharmaceuticals, Inc. (March 22, 2001)	802, 408, 901
180			DDX-122 (O'Neill)	ABB_SIM00565498 - ABB_SIM00565501	06/22/2001	Correspondence regarding Senior management NPU meeting notes with enclosure (Sr. Management New Product Update 6/19/01)	802, 901, 402
181			DDX-123 (O'Neill)	ABB_SIM00565502 - ABB_SIM00565504	07/27/2000	Meeting Minutes: Niacin ER, Team Meeting, 07/25/2000	802, 901, 402
182			DDX-124 (O'Neill)	ABB_SIM00565505 - ABB_SIM00565511	10/26/2000	Meeting Minutes: Niacin ER, Team Meeting, 10/24/2000 with handwritten notes	802, 901, 402
183			DDX-125 (O'Neill)	ABB_SIM00565512 - ABB_SIM00565513	08/19/1997	Letter from Cecil Schmidt, Attorney, Merchant & Gould, to Peter Manso, Jenkens & Gilchrist (August 19, 1997)	802, 901, 402
184			DDX-126 (O'Neill)	ABB_SIM00565514 - ABB_SIM00565539	01/09/2002	Patent Purchase and Assignment Agreement between Upsher-Smith Laboratories, Inc. and Kos Pharmaceuticals, Inc.	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
185			DDX-127 (O'Neill)	ABB_SIM00565540 - ABB_SIM00565542	09/07/1990	Letter from Edwin Hedblom, Project Manager, Upsher-Smith Laboratories, Inc., to Robert Knopp, Northwest Lipid Research Clinic (September 7, 1990)	802, 901
186			DDX-128 (O'Neill)	ABB_SIM00565543 - ABB_SIM00565545	08/12/1997	Memorandum regarding Niacor SR with handwritten notes	802, 901
187			DDX-129 (O'Neill); L-194 (McGovern)	ABB_SIM00565546 - ABB_SIM00565556	11/29/2001	Brown, et al., *Simvastatin and Niacin, Antioxidant Vitamins, or the Combination for the Prevention of Coronary Disease,* 345 N. Engl J. Med., pp. 1583-1592 (2001)	
188			DDX-130 (O'Neill)	ABB_SIM00565557 - ABB_SIM00565560	12/16/1991	Lavie, et al., *Marked Benefit with Sustained-Release Naicin Therapy in Patients with "Isolated" Very Low Levels of High-Density Lipoprotein Cholesterol and Coronary Artery Disease,* 69 Am. J. Cardiol., pp. 1083-1085 (1992)	403 (cumulative)
189			DDX-131 (O'Neill)	ABB_SIM00565561 - ABB_SIM00565567	03/13/1997	Brown, et al., *Moderate Dose, Three-Drug Therapy with Niacin, Lovastatin, and Colestipol to Reduce Low-Density Lipoprotein Cholesterol <100 mg/dl in Patients with Hyperlipidemia and Coronary Artery Disease,* 80 Am. J. Cardiol., pp. 111-115 (1997)	403 (cumulative)
190			DDX-132 (O'Neill)	ABB_SIM00565568 - ABB_SIM00565573	09/01/1992	Squires, et al., *Low-Dose, Time-Release Nicotinic Acid: Effects in Selected Patients with Low Concentrations of High-Density Lipoprotein Cholesterol,* 67 Mayo Clin. Proc., pp. 855-860 (1992)	403 (cumulative), Lack of foundation for date description
191			DDX-133 (O'Neill)	ABB_SIM00565574 - ABB_SIM00565580	08/15/1994	Gray, et al., *Efficacy and Safety of Controlled-Release Niacin in Dyslipoproteinemic Veterans,* 121 Ann. Intern. Med., pp. 252-258 (1994)	403 (cumulative)
192			DDX-129 (Balandis)	ABB_SIM00529098 - ABB_SIM00529100	10/14/2003	Kos v. Barr: Barr's First Amended Notice of Deposition for Suzanne Balandis	402
193			DDX-130 (Balandis)	ABB_SIM00529101 - ABB_SIM00529148	11/30/1999	Correspondence from Suzanne Balandis with enclosure (Epidemiology of Low HDL, PowerPoint Presentation, David Maron, M.D.)	802
194			DDX-131 (Balandis)	ABB_SIM00529149 - ABB_SIM00529173		Formulation Development Report, Niaspan Tablets (DRAFT)	
195			DDX-132 (Balandis)	ABB_SIM00529174 - ABB_SIM00529184	02/08/1990	Protocol Number 89/03: A Single Dose, Three-Way Crossover, Pilot Bioavailability Study Comparing Immediate Release Niacin and Two Sustained Release Niacin Formulations	
196			DDX-133 (Balandis)	ABB_SIM00529185 - ABB_SIM00529250	03/03/1991	Protocol Number 91/01: A Three-Way Crossover Study of the Bioavailability of Niacin From a Sustained Release Formulation When Dosed in the Fed Versus Fasted States in Reference to an Immediate Release Formulation	
197			DDX-134 (Balandis)	ABB_SIM00529251 - ABB_SIM00529256	10/10/1995	Internal Memorandum regarding Minutes of Niaspan™ Project Meeting	
198			DDX-135 (Balandis)	ABB_SIM00529257 - ABB_SIM00529259	03/30/1992	Internal Memorandum regarding Minutes of Niaspan™ Update Meeting	
199			DDX-136 (Balandis)	ABB_SIM00529260	03/30/1999	Correspondence from Mark McGovern regarding Search Request	106, 802, 402

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
200			DDX-137 (Balandis)	ABB_SIM00529261 - ABB_SIM00529264	04/06/1999	Correspondence from Patricia Kim regarding Information Request	802, 402
201			DDX-138 (Balandis)	ABB_SIM00529265 - ABB_SIM00529280		Correspondence from Marijke Adams, project director, Kos Pharmaceuticals, regarding labeling with enclosures	802
202			DDX-139 (Balandis)	ABB_SIM00529281 - ABB_SIM00529282		Handwritten notes	402, 403, 802
203			DDX-140 (Patel)	ABB_SIM00529283 - ABB_SIM00529292	06/30/1998	U.S. Patent No. 5,773,453	403 (cumulative), Lack of foundation for date description
204			DDX-141 (Patel)	ABB_SIM00529293	07/16/1997	Letter from Mukesh Patel, Director of Licensing, Kos Pharmaceuticals, Inc. to Monté Partee, Associate Director, Bristol-Myers Squibb Company (July 16, 1997)	
205			DDX-142 (Patel)	ABB_SIM00529294	08/04/1997	Letter from Monté Partee, Associate Director, Bristol-Myers Squibb Company to Mukesh Patel, Director of Licensing, Kos Pharmaceuticals, Inc. (August 4, 1997	802
206			DDX-143 (Patel)	ABB_SIM00529295	03/09/1999	Internal Memorandum regarding Patent concerning the co-administration of 10-160mg of aspirin and niacin	
207			DDX-144 (Patel)	ABB_SIM00529296 - ABB_SIM00529299	08/11/1992	Facsimile to David Bova with enclosure (Kos Pharmaceuticals, Inc., Summary of Development Projects)	403 (cumulative)
208			DDX-145 (Patel)	ABB_SIM00529300 - ABB_SIM00529305	08/13/1994	Internal Memorandum regarding R&D Project Update	403 (cumulative)
209			DDX-146 (Patel)	ABB_SIM00529306 - ABB_SIM00529310	10/14/1994	Correspondence from Daniel M. Bell with enclosure (Interoffice Memo regarding Kos Pharmaceuticals Niacin-Niaspan Results of Focus Group dated September 19, 1994)	
210			DDX-147 (Patel)	ABB-SIM00529311	11/06/1997	Conference Call with SmithKline Beecham, Outstanding Technical & Commercial Review Matters with handwritten notes	
211			DDX-148 (Patel)	ABB_SIM00529312	04/08/1998	Correspondence from Mukesh Patel regarding Astra Draft Proposal	106, 402
212			DDX-149 (Patel)	ABB_SIM00529313	05/18/1998	Memorandum regarding Novartis	802
213			DDX-150 (Patel)	ABB_SIM00529314 - ABB_SIM00529316	09/21/1998	Correspondence from Mukesh Patel regarding Astra with enclosures	802
214			DDX-151 (Patel)	ABB_SIM00529317	04/09/1999	Correspondence from Gene Kotz regarding Teleconference with handwritten notes	802, 901 as to handwriting
215			DDX-152 (Patel)	ABB_SIM00529318 - ABB_SIM00529323	03/15/2000	Letter from Stephen W. Potter, Senior Vice President, DuPont Pharmaceuticals Co. to Michael Jaharis, Chairman and CEO, Mukesh Patel, Vice President - Licensing, Christopher Kiritsy, Kos Pharmaceuticals, Inc. with enclosure	802
216			DDX-153 (Patel)	ABB_SIM00529324	03/29/2000	Letter from Nicole Oswald, Kos Pharmaceuticals, Inc. to Barbara Saunders, Associate General Counsel, DuPont Pharmaceuticals Company regarding Niaspan® and Nicostatin™ Alliance	106, 402

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
217			DDX-154 (Patel)	ABB_SIM00529325 - ABB_SIM00529326	04/03/2000	Letter from Peter Manso, Akerman, Senterfitt & Eidson, P.A., to Ken Rubin, DuPont Pharmaceuticals Co. regarding KOS U.S. Patent Applications: USSN 08/368,378; and USSN 08/814,974	402
218			DDX-155 (Patel)	ABB_SIM00529327	08/27/1999	Letter from Mukesh Patel, Vice President, Licensing, Kos Pharmaceuticals, Inc., to Gene Kotz, Senior Director, DuPont Pharmaceuticals Co. with handwritten notes	
219			DDX-156 (Bova)	ABB_SIM00529328	01/19/1989	Letter to Dr. Ernst Schaefer, Tufts University	106, 403 (cumulative)
220			DDX-157 (Bova); SIM-003 (Bova)	ABB_SIM00529329 - ABB_SIM00529336	03/08/1989	Clinical Study Outline for Nicotinic Acid/Aspirin Study	
221			DDX-158 (Bova)	ABB_SIM00529337 - ABB_SIM00529340	03/27/1996	USPTO Declaration of David J. Bova regarding Serial No. 08/368,378	403 (cumulative)
222			DDX-159 (Bova)	ABB_SIM00529341 - ABB_SIM00529345	01/06/1998	USPTO Declaration of David J. Bova regarding Serial No. 08/814,974	403 (cumulative)
223			DDX-160 (Bova)	ABB_SIM00529346 - ABB_SIM00529363	08/01/1991	Study 89/04 Final Report: A Single-Blind Placebo Controlled Pilot Study Comparing the Effect of Once-A-Day Versus Twice-A-Day Dosing of Niaspan™ on Serum Lipids	Lack of foundation for date description
224			DDX-161 (Bova); SIM-019 (Bova)	ABB_SIM00529364 - ABB_SIM00529537	04/28/1991	Study 91/01 Final Report: A Three-Way Crossover Study of the Bioavailability of Niacin from a Sustained-Release Formulation When Dosed in the Fed Versus Fasted States in Reference to an Immediate-Release Formulation	
225			DDX-162 (Bova)	ABB_SIM00529538 - ABB_SIM00529700	03/21/1994	Study 91/02 Final Report: A Pilot Efficacy Study of a Once-A-Day Sustained-Release Niacin Formulation (Niaspan™) in the Treatment of Primary Type IIa Hyperlipidemia	
226			DDX-163 (Bova)	ABB-SIM00529701 - ABB_SIM00529750	01/31/1991	Protocol Number 91/02: A Pilot Efficacy Study of a Once-A-Day Sustained Release Niacin Formulation (Niaspan™) in the Treatment of Primary Type IIa Hyperlipidemia	
227			DDX-164 (Bova)	ABB_SIM00529751 - ABB_SIM00529790		Protocol Number 91/04: A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan™ (Sustained-Release Niacin) in Patients with Primary Hyperlipoproteinemia	
228			DDX-165 (Bova)	ABB-SIM00529791 - ABB_SIM00529850	08/23/1991	Protocol Number 91/04: A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan™ (Sustained-Release Niacin) in Patients with Primary Hyperlipoproteinemia	
229			DDX-166 (Bova)	ABB_SIM00529851 - ABB_SIM00529861	12/23/1992	Physicians' Desk Reference, 47th edition (1993): excerpts	106, 403 (cumulative)
230			DDX-167 (Bova)	ABB_SIM00529862 - ABB_SIM00529868	11/17/1989	Facsimile to George Toth with enclosures	
231			DDX-168 (Bova); SIM-022 (Bova)	ABB_SIM00529869 - ABB_SIM00530027	04/25/1996	Protocol Number 91/04 Final Report (Revised): A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan™ in Patients with Primary Hyperlipoproteinemia	
232			DDX-169 (Bova)	ABB_SIM00530028 - ABB_SIM00530040	7/17/1989 - 5/19/1992	Report/Study No.: PESR960012, Granulation Development Chart	106

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
233			DDX-170 (Bova); SIM-353 (Williams)	ABB_SIM00530041 - ABB_SIM00530217	03/26/1990	Kos Pharmaceuticals, Inc.'s IND Application regarding Niaspan™ (Sustained Release Niacin), Reduction of elevated total and LDL cholesterol levels	403 (cumulative)
234			DDX-171 (Bova); SIM-051 (Cefali)	ABB_SIM00530218 - ABB_SIM00530225	07/01/1992	Labeling Guidance, Revised July 1992: Niacin Tablets USP	Lack of foundation for date description
235			DDX-172 (Bova)	ABB_SIM00530226 - ABB_SIM00530230	01/21/2000	Correspondence from Margaret Miller regarding Call bag with enclosure	802
236			DDX-173 (Bova)	ABB_SIM00530231		Medline Search on Niacin, 1988-Present	802
237			DDX-174 (Bova)	ABB_SIM00530232 - ABB_SIM00530250	12/20/1996	Kos Pharmaceuticals, Inc. Amendment of Patent Information Claim for Exclusivity Niaspan® (controlled release niacin) tablets regarding NDA 20-381	402
238			DDX-175 (Bova)	ABB_SIM00530251 - ABB_SIM00530254	12/16/1991	Lavie, et al., Marked Benefit with Sustained-Release Naicin Therapy in Patients with "Isolated" Very Low Levels of High-Density Lipoprotein Cholesterol and Coronary Artery Disease, 69 Am. J. Cardiol., pp. 1083-1085 (1992)	
239			DDX-176 (Bova)	ABB_SIM00530255 - ABB_SIM00530314	11/20/1998	USPTO Amendment After October 28, 1998 Interview regarding Serial No. 08/814,974	106
240			DDX-177 (Bova)	ABB_SIM00530315		Handwritten notes	802, 901
241			DDX-178 (Bova); SIM-046 (Cefali)	ABB_SIM00530316 - ABB_SIM00530468	04/30/1996	Protocol Number 91/15 Final Report (Revised): A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan™ - A Dose-Escalation Study	
242			DDX-179 (Bova); SIM-034 (Cefali); SIM-218 (Bottorff)	ABB_SIM00530469 - ABB_SIM00530774	10/16/1995	Protocol Number 94/10 Final Report: The Pharmacokinetics of Niacin and its Three Major Metabolites Following Multiple-Dose Administration of Niaspan™ at 1000mg, 1500mg, 2000mg and 3000mg Doses	
243			DDX-180 (Bova)	ABB_SIM00530775 - ABB_SIM00530784	10/11/1996	Report/Study No.: PESR960010, Title: A 500mg Niacin Comparative Dissolution Study	
244			DDX-181 (Bova)	ABB_SIM00530785 - ABB_SIM00530825	01/15/1997	Protocol Number 96/01 Final Report: The Comparative Bioavailability of Two Sustained-Release Niacin Products Relative to Niaspan®	
245			DDX-182 (Ferder)	ABB_SIM00530826 - ABB_SIM00530830	10/10/2003	Kos v. Barr: Subpoena to Forest Pharmaceuticals, Inc. (for testimony)	402
246			DDX-183 (Ferder)	FPI000003	08/17/1993	Interoffice Memorandum regarding 510410 Niac Capsules	802
247			DDX-184 (Ferder)	FPI000002	07/06/1989	Product Label	Lack of foundation for date description
248			DDX-185 (Ferder)	FPI000001	11/25/1991	Product Label	
249			DDX-186 (Ferder)	FOREST0064 - FOREST0113	N/A	Compilation of Forest Pharmaceuticals Price Lists	
250			DDX-187 (Ferder)	FPI000004 - FPI000008	11/07/2002	Interoffice Memorandum regarding Documents Related to Niac Capsules with enclosures	802
251			DDX-188 (Ferder)	FOREST0054 - FOREST0063	N/A	Declaration of Thomas Ferder & Attachments	802

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
252			DDX-189 (Malhotra)	ABB_SIM00565077 - ABB_SIM00565079	08/28/2003	Kos v. Barr: Notice of Deposition (Kuldip R. Malhotra)	402
253			DDX-190 (Malhotra)	ABB_SIM00565080 - ABB_SIM00565099	09/11/2003	Kos v. Barr: Mr. Kuldip R. Malhotra's Objections to Barr's August 28, 2003 Subpoena	402
254			DDX-191 (Malhotra)	ABB_SIM00565100 - ABB_SIM00565103		Notes regarding gel formation and Slo-Niacin	106, 802, 402
255			DDX-192 (Malhotra)	ABB_SIM00565104 - ABB_SIM00565120	10/3/1988 - 10/27/1988	Incomplete, half-page notebook excerpts with handwritten notes	106, 802, 402
256			DDX-307 (Kropp)	N/A	05/19/2003	Kos v. Barr: Subpoena to Pharmavite LLC (for documents)	402
257			DDX-308 (Kropp)	N/A	10/10/2003	Kos v. Barr: Subpoena to Pharmavite LLC (for testimony)	402
258			DDX-309 (Kropp)	Pharmavite000227 - Pharmavite000228	02/09/1990	Thayer, Timed Release Niacin 250mg Product Label (with handwritten notes)	802, Lack of foundation for date description
259			DDX-310 (Kropp)	Pharmavite000229	08/02/1990	Spring Valley, Timed Release Niacin 250mg Product Label (with handwritten notes)	Lack of foundation for date description
260			DDX-311 (Kropp)	N/A	10/22/2003	Email from Steve Day regarding Response to ACR10273 for David Kropp	802
261			DDX-312 (Kropp)	Pharmavite000286 - Pharmavite000288	02/22/1989	Walgreen's, Timed Release Niacin 500mg Product Label (with handwritten notes)	802, Lack of foundation for date description
262			DDX-313 (Kropp)	Pharmavite000232 - Pharmavite000233	05/18/1989	Good Neighbor Pharmacy, Timed Release Niacin 250mg Product Label (with handwritten notes)	Lack of foundation for date description
263			DDX-314 (Kropp)	Pharmavite000239 - Pharmavite000242	08/02/1990	Brooks, Timed Release Niacin 500mg Product Label (with handwritten notes)	802, Lack of foundation for date description
264			DDX-315 (Kropp)	Pharmavite000276 - Pharmavite000278	8/1/1990	Good Neighbor Pharmacy, Timed Release Niacin 500mg Product Label (with handwritten notes)	Lack of foundation for date description
265			DDX-316 (Kropp)	Pharmavite000279 - Pharmavite000280	08/01/1990	Health Mart, Timed Release Niacin 500mg Product Label (with handwritten notes)	Lack of foundation for date description
266			DDX-200 (Cefali); SIM-041 (Cefali)	ABB_SIM00530875 - ABB_SIM00530880	09/14/1995	Kos Niaspan Study 94/10 - Urine % Dose Recovered Analysis	
267			DDX-201 (Cefali)	ABB_SIM00530881 - ABB_SIM00530882	02/27/1996	Morgan, et al., *Safe and Effective Treatment of Dyslipidmia by Niaspan*™, A New Sustained-Release Niacin, 59(2) Clin. Pharm. Ther., PII-30 (1996)	
268			DDX-202 (Cefali)	ABB_SIM00530883 - ABB_SIM00530890	01/01/1996	Morgan, et al., *Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial,* 1(3) J. Cardiovasc. Pharmacol. Therapeut., pp. 195-202 (1996)	Lack of foundation for date description
269			DDX-203 (Cefali)	ABB_SIM00530891 - ABB_SIM00530895		A copy of the prosecution history leading up to the '715 patent	106, 403 (cumulative)
270			DDX-204 (Cefali)	ABB_SIM00530896 - ABB_SIM00530901	10/21/2003	Kos v. Barr: Barr Laboratories, Inc.'s Second Amended Notice of Deposition Pursuant to Rule 30(b)(6)	402

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
271			DDX-205 (Cefali); SIM-042 (Cefali)	ABB_SIM00530902 - ABB_SIM00530903	03/27/1997	Internal Memorandum regarding Report from meeting with Dr. Peter Guengerich	802
272			DDX-206 (Cefali); SIM-043 (Cefali)	ABB_SIM00530904 - ABB_SIM00530905	04/07/1997	Internal Memorandum regarding Report from meeting with Dr. David Jollow	802
273			DDX-207 (Cefali); SIM-038 (Cefali)	ABB_SIM00530906 - ABB_SIM00530911	08/06/1997	National Sales Meeting, August 6, 1997, Niaspan® Delivery System	
274			DDX-208 (Cefali)	ABB_SIM00530912 - ABB_SIM00530939	06/17/1997	Protocol Number 96/08 Final Report: The Comparative Bioavailability of Three Formulations of Sustained-Release Niacin Relative to Niaspan®	
275			DDX-209 (Cefali)	ABB_SIM00530940 - ABB_SIM00531010	07/06/1995	Protocol Number 94/07 Draft Report: Investigation of the Effect of Sustained-Release Niacin on Serum Transaminases and Phosphorus	
276			DDX-300 (Lanigan)	N/A	10/10/2003	Kos v. Barr: Subpoena to Leiner Health Products (for testimony)	402
277			DDX-301 (Lanigan)	Leiner000275 - Leiner000276		YourLife®, Timed Release Niatrol 500mg Product Label	
278			DDX-302 (Lanigan)	Leiner000262 - Leiner000274		Collection of Product Labels	802
279			DDX-303 (Lanigan)	Leiner000124 - Leiner000125	10/10/1988	Leiner Nutritional Products Corp., Bulk Purchasing Specification for Time Release Niacin 250mg	
280			DDX-304 (Lanigan)	Leiner000372 - Leiner000373	10/28/2003	Leiner Health Products T.R. Niacin Sales - 250mg and 500mg - FY1988 - FY1994 - Sales in $000's	Lack of foundation for date description
281			DDX-305 (Lanigan)	Leiner000279		Vons Natural, Time Release Niacin 250mg Product Label	802
282			DDX-210 (DiStefano)	ABB_SIM00531011 - ABB_SIM00531056	04/24/1996	Protocol Number 89/04 Final Report (Revised): A Single-Blind Placebo-Controlled Pilot Study Comparing the Effect of Once-A-Day Versus Twice-A-Day Dosing of Niaspan™ on Serum Lipids	
283			DDX-211 (DiStefano)	ABB_SIM00531057 - ABB_SIM00531066	1/13/1992	Final Protocol 91/04: Appendix 1, Informed Consent Form	
284			DDX-212 (DiStefano)	ABB_SIM00531067 - ABB_SIM00531075	01/13/1992	Final Protocol 91/05: Appendix 1, Informed Consent Form	
285			DDX-213 (DiStefano)	ABB_SIM00531076 - ABB_SIM00531085		Protocol 96/05: Appendix A, Informed Consent Form	
286			DDX-214 (Straughn)	ABB_SIM00531086 - ABB_SIM00531112	05/12/2003	Curriculum Vitae (A. B. Straughn, Pharm.D.)	402, 802
287			DDX-215 (Straughn)	ABB_SIM00531113 - ABB_SIM00531119	11/05/2003	Kos v. Barr: Subpoena to Dr. Arthur B. Straughn (for documents and testimony)	402
288			DDX-216 (Straughn); SIM-010 (Bova)	ABB_SIM00531120 - ABB_SIM00531125	12/21/1988	Letter from Arthur B. Straughn, Professor and Clinical Director, The University of Tennessee Memphis to David J. Bova (December 21, 1988) with enclosure	802

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
289			DDX-217 (Straughn)	ABB_SIM00531126	02/28/1989	Letter from David J. Bova. to Arthur Straughn, The University of Tennessee (February 28, 1989) with enclosure	
290			DDX-218 (Straughn)	ABB_SIM00531127 - ABB_SIM00531216	11/13/1998	USPTO Declaration of Arthur B. Straughn, Pharm. D. regarding Serial No. 08/814,974	106, 403 (cumulative)
291			DDX-219 (Straughn); SIM-215 (Bottorff)	ABB_SIM00531217 - ABB_SIM00531258	01/20/1997	Protocol Number 96/01 Final Report: The Comparative Bioavailability of Two Sustained-Release Niacin Products Relative to Niaspan®	
292			DDX-220 (Straughn)	ABB_SIM00531259 - ABB_SIM00531273		Printed statistical data from SAS	802
293			DDX-221 (Straughn)	ABB_SIM00531274 - ABB-SIM00531291		Printed statistical data from SAS	802
294			DDX-222 (Straughn)	ABB_SIM00531292	01/15/1997	Table 5. Percent of Niacin Dose in Urin as Niacin and Metabolites	106
295			DDX-223 (McGovern)	ABB_SIM00531293 - ABB_SIM00531300	01/01/1990	Issues in Cholesterol Management: Reappraisal of Niacin	Lack of foundation for date description
296			DDX-224 (McGovern)	ABB_SIM00531301 - ABB_SIM00531302	08/22/2003	Letter from Robert Wilson, Fish & Neave, to Lynn Ulrich, Winston & Strawn (August 22, 2003) regarding Mark McGovern deposition notices (personal capacity and 30(b)(6))	402
297			DDX-225 (McGovern)	ABB_SIM00531303 - ABB_SIM00531305	02/01/2002	Van, et al., *Comparison of Extended-Release Niacin and Atorvastatin Monotherapies and Combination Treatment of the Atherogenic Lipid Profile in Diabetes Mellitus,* 89(11) Am. J. Cardiol., pp. 1306-1308 (2002)	Lack of foundation for date description
298			DDX-226 (McGovern)	ABB_SIM00531306 - ABB_SIM00531313	09/13/2000	Elam, et al., *Effect of Niacin on Lipid and Lipoprotein Levels and Glycemic Control in Patients with Diabetes and Peripheral Arterial Disease, The ADMIT Study: A Randomized Trial,* 284 JAMA, pp. 1263-1270 (2000)	
299			DDX-227 (McGovern)	ABB_SIM00531314 - ABB_SIM00531317	09/01/1990	Wu, et al., *Promotion of extended-release niacin tablets at a Veterans Affairs medical center,* 47 Am. J. Hosp. Pharm., pp. 2031-2034 (1990)	Lack of foundation for date description
300			DDX-228 (McGovern)	ABB_SIM00531318 - ABB_SIM00531324	12/01/1998	Memorandum regarding Niaspan and gemfibrozil with enclosures	802
301			DDX-230 (Greathouse)		10/15/2003	Kos v. Barr: Subpoena to Aventis Pharmaceuticals, Inc. (for documents and testimony)	402
302			DDX-231 (Greathouse)	AVN005547 - AVN005554	01/12/1982	Inter-office correspondence regarding Nicobid Labels with attachments	802
303			DDX-232 (Greathouse)	AVN000240 - AVN000269	10/25/1991	RhÔne-Poulenc Rorer, Inc., Label Specification regarding Nicobid 500mg Capsules - 500's	802
304			DDX-233 (Greathouse)	AVN000857 - AVN000858	01/01/1985	Nicobid (niacin, USV) brochure	802, Lack of foundation for date description
305			DDX-234 (Greathouse)	AVN000862 - AVN000871	07/30/1987	Correspondence from Dave Hotchkiss regarding JAMA Article	1002
306			DDX-235 (Greathouse)	AVN006564 - AVN006689	Undated	Protocol No.: 83,823-1A(2), Nicobid/Nicolar & Study Summary	802

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
307			DDX-236 (Greathouse)	AVN002191 - AVN002202	01/27/1988	Rorer Interoffice Correspondence regarding Revised Nicobid Forecast	802
308			DDX-237 (Greathouse)	AVN002204 - AVN002218	01/01/1982	Hyperlipidemia Compendium	802, Lack of foundation for date description
309			DDX-238 (Greathouse)	AVN007329 - AVN007335	12/28/1973	Parsons, *Effect of Nicobid on Serum Lipid Levels in Hyperlipidemic Individuals,* Final Report of Findings and Conclusions (1973)	802
310			DDX-239 (Greathouse)	AVN007560 - AVN007563	11/10/1988	Protocol RG-83624-101, Informed Consent Form	802
311			DDX-240 (Greathouse)	AVN002167 - AVN002190	02/01/1988	Rorer Interoffice Correspondence regarding Lipid Reduction Market Forecast	802
312			DDX-385 (Manso)	ABB_SIM00531543 - ABB_SIM00531558	11/03/1997	Letter from Peter Manso, Jenkens & Gilchrist, to Daniel Bell and Eugenio Cefali, Kos Pharmaceuticals, Inc. regarding U.S. Patent Applications relating to the biopharmaceutical characteristics of Niaspan	106, 403 (cumulative)
313			DDX-386 (Manso)	ABB_SIM00531559 - ABB_SIM00531912	01/14/1995	File History regarding Serial No. 08/368,378 (U.S. Patent No. 8,080,428)	403 (cumulative), Lack of foundation for date description
314			DDX-387 (Manso)	ABB_SIM00531913	11/07/2001	Email from Ralph Palo regarding Due Diligence	802
315			DDX-388 (Manso)	ABB_SIM00531914 - ABB_SIM00532259	Undated	USPTO excerpts of the file history for the '974 application that issued as the '930 patent	106, 403 (cumulative)
316			DDX-389 (Manso); SIM-006 (Bova); SIM-337 (Williams)	ABB_SIM00532261 - ABB_SIM00532314	09/20/2000	Document Request Form for Development Report regarding PESR960012, Formulation & Process Development Report, Niaspan	
317			DDX-390 (Manso)	ABB_SIM00532315 - ABB_SIM00532639	Undated	USPTO excerpts of the file history for the '974 application that issued as the '930 patent	106, 403 (cumulative)
318			DDX-391 (Manso)	ABB_SIM00532640	03/11/2003	USPTO Certificate regarding Patent No. 6,406,715	106, 403 (cumulative)
319			DDX-392 (Manso)	ABB_SIM00532641 - ABB_SIM00532657	01/20/1997	Protocol Number 96/01 Final Report: The Comparative Bioavailability of Two Sustained-Release Niacin Products Relative to Niaspan®	106
320			DDX-393 (Manso)	ABB_SIM00532658 - ABB_SIM00532841	10/31/1997	File History regarding Serial No. 08/962,423	403 (cumulative)
321			DDX-394 (Manso)	ABB_SIM00532842 - ABB_SIM00532846	10/19/1995	Protocol Number 94/08 Final Report: Abstract (excerpt)	106, 403 (cumulative)
322			DDX-395 (Manso)	ABB_SIM00532847 - ABB_SIM00532855	11/22/1995	Protocol Number 94/09 Final Report: Abstract (excerpt)	106, 403 (cumulative)
323			DDX-396 (Manso)	ABB_SIM00532856 - ABB_SIM00532860	11/07/1995	Protocol Number 95/01 Final Report: Abstract (excerpt)	106, 403 (cumulative)
324			DDX-397 (Manso)	ABB_SIM00532861 - ABB_SIM00532983	03/06/1997	File History regarding Serial No. 08/814,974 (U.S. Patent No. 6,129,930)	403, Lack of foundation for date description

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
325			DDX-241 (Messick)	ABB_SIM00531333 - ABB_SIM00531448	09/10/2003	Kos v. Barr: Deposition Transcript of Karen Messick	802
326			DDX-242 (Messick)	ABB_SIM00531449	02/25/2002	Letter from Paul Busse, Faegre & Benson LLP, to Rodney Bell, Holland & Knight LLP (February 25, 2002)	802
327			DDX-243 (Messick)	ABB_SIM00531450 - ABB_SIM00531490	10/29/2003	Co-Promotion Agreement between Kos Pharmaceuticals, Inc. and Takeda Pharmaceuticals North America, Inc.	
328			DDX-244 (Messick)	ABB_SIM00531491 - ABB_SIM00531492	11/03/1997	Letter from Peter Manso, Jenkens & Gilchrist, to Daniel Bell and Eugenio Cefali, Kos Pharmaceuticals, Inc. regarding U.S. Patent Applications relating to the biopharmaceutical characteristics of Niaspan	106, 403 (cumulative)
329			DDX-245 (Messick)	ABB_SIM00531493 - ABB_SIM00531494	10/30/2002	Email from William Gentry regarding ACCP abstract update	802
330			DDX-246 (Messick)	ABB_SIM00531495	11/20/2000	Handwritten notes	402, 802, 901
331			DDX-247 (Messick)	ABB_SIM00531496 - ABB_SIM00531499	11/10/2000	Interoffice Memorandum regarding U.S. Federal Trade Commission Conference Call	402
332			DDX-248 (Messick)	ABB_SIM00531500 - ABB_SIM00531506	3/22/1996 - 12/19/2000	Contact list	
333			DDX-249 (O'Neill)	ABB_SIM00564948 - ABB_SIM00564952	06/22/2004	Kos v. Barr: Subpoena to Upsher-Smith Laboratories, Inc. (for testimony)	402
334			DDX-250 (O'Neill)	ABB_SIM00564953	09/15/1997	Email from Lori Freese regarding KOS Response Meeting with handwritten notes	802, 901
335			DDX-251 (O'Neill)	ABB_SIM00564954 - ABB_SIM00564963		Internal Upsher-Smith Laboratories, Inc. document	802, 901
336			DDX-252 (O'Neill)	ABB_SIM00564964	01/01/1992	Dear Doctor Letter from Harvey Arbit, Director of Medical Affairs, Upsher-Smith Laboratories, Inc.	802, 901, Lack of foundation for date description
337			DDX-253 (O'Neill)	ABB_SIM00564965		Niacor-SR® Tablets (polygel™ controlled-release niacin)	802, 901
338			DDX-254 (O'Neill)	ABB_SIM00564966 - ABB_SIM00564969		Niacor SR Dissolution Profiles Comparison Charts	802, 901
339			DDX-255 (O'Neill)	ABB_SIM00564970 - ABB_SIM00565000		Internal Upsher-Smith Laboratories, Inc. document regarding Comparative Dissolutions	802, 901
340			DDX-256 (O'Neill)	ABB_SIM00565001 - ABB_SIM00565003		Frequency Tables of Dissolution Data, Niaspan and Niacin ER Tablets 500mg	802, 901
341			DDX-257 (O'Neill)	ABB_SIM00565004 - ABB_SIM00565016		Niaspan 1000mg and 750mg Tablets Data	802, 901
342			DDX-258 (O'Neill)	ABB_SIM00565017 - ABB_SIM00565020		Dissolution Data of Niacor SR (various strengths and shapes of tablets)	802, 901
343			DDX-259 (O'Neill)	ABB_SIM00565021		Niacor SR Dissolution, Lot 106.30 and Lot 106.31	802, 901
344			DDX-260 (O'Neill)	ABB_SIM00565022 - ABB_SIM00565024		Representative Dissolution Profiles, Niacor-SR 250mg and 500mg Tablet Dissolution Profiles	802, 901

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
345			DDX-261 (O'Neill)	ABB_SIM00565025 - ABB_SIM00565026		Handwritten notes entitled Niacin ER (Niaspan Generic) including discussion of Niaspan ER	802, 901
346			DDX-262 (O'Neill)	ABB_SIM00565027 - ABB_SIM00565037		Handwritten notes entitled Niacor SR	802, 901
347			DDX-263 (O'Neill)	ABB_SIM00565038 - ABB_SIM00565040	01/18/1990	Upsher-Smith Interoffice Memorandum regarding Brief notes from appointments with Dr. Kottke on January 16, 1990	802, 901
348			DDX-264 (O'Neill)	ABB_SIM00565041 - ABB_SIM00565070		Dissolution data with handwritten notes	802, 901
349			DDX-265 (O'Neill)	ABB_SIM00565071 - ABB_SIM00565076	10/24/2000	Niacin ER, Team Meeting, 10/24/00	802, 901
350			DDX-266 (Cefali)	ABB_SIM00534576 - ABB_SIM00534602	06/08/2004	U.S. Patent No. 6,746,691	403 (cumulative), Lack of foundation for date description
351			DDX-267 (Cefali)	ABB_SIM00534603 - ABB_SIM00534610	08/05/1998	1000mg, 750mg, 500mg and 375mg Niaspan Tablets - absolute % difference	
352			DDX-268 (Cefali)	ABB_SIM00534611 - ABB_SIM00534613		Hollywood Production Lots, 12 summary	
353			DDX-269 (Cefali)	ABB_SIM00534614 - ABB_SIM00534625	09/15/1995	Summary of Niaspan™ Tablet Strengths Used in Clinical Studies, by Lot Number (with various lab notebook excerpts)	
354			DDX-270 (Cefali)	ABB_SIM00534626 - ABB_SIM00534631	1996-1997	500mg, 750mg, 325mg and 1000mg Niaspan Tablets, Clinical and Production Lots	
355			DDX-271 (Cefali); SIM-196 (Toth)	ABB_SIM00534632 - ABB_SIM00534640	07/07/1997	Internal Memorandum regarding *In Vitro - In Vivo* Correlation of Niaspan Using F2 Criteria in Lieu of Bioequivalence Studies Following Minor Changes in Formulation or Changes in Manufacturing Site	
356			DDX-272 (Cefali)	ABB_SIM00534641 - ABB_SIM00534651		Handwritten Notes and draft letter to the FDA	
357			DDX-273 (Cefali)	ABB_SIM00534652 - ABB_SIM00534664	08/18/1995	Letter from Donald Raineri, Associate Director - Regulatory Affairs, Kos Pharmaceuticals, Inc. to Stephen Trostle, Consumer Safety Officer, FDA with related facsimile and interoffice memorandum correspondence enclosures	
358			DDX-275 (Cefali)	ABB_SIM00534665 - ABB_SIM00534709		Kos Pharmaceuticals, Niaspan F2 Report prepared by Arthur B. Straughn, Pharm. D., University of Tennessee, Memphis	
359			DDX-276 (Cefali)	ABB_SIM00534710 - ABB_SIM00534713	07/14/1997	Internal Memorandum regarding F2 Criteria of the Production Lots	403 (cumulative)
360			DDX-276 (Cefali); SIM-351 (Williams)	ABB_SIM00534714 - ABB_S3_00534717	07/14/1997	Internal Memorandum regarding F2 Criteria of the Production Lots	403 (cumulative)
361			DDX-277 (Cefali)	ABB_SIM00534718 - ABB_SIM00534731	11/20/1997	Facsimile from Karen DiStefano regarding F2 Values and Rationale for Waiver of BE for Niaspan® Site Change	
362			DDX-278 (Cefali)	ABB_SIM00534732 - ABB_SIM00534734	05/05/1998	Internal Memorandum regarding Conversation with Mike Fossler, Ph.D. on April 23, 1998, regarding Bioequivalence Studies Required to Qualify the Edison Site for Niaspan®	802

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
363			L-001 (Cefali)	ABB_SIM00682572 - ABB_SIM00682574	11/14/2008	Letter agreement between Abbott Laboratories and E.A. Cefali Pharmaceutical Consulting, LLC	
364			L-006 (Cefali)	ABB_SIM00682949 - ABB_SIM00683048	11/22/1995	Protocol Number 94/09 Final Report: The Comparative Bioavailability of 500mg and 750mg Tablet Strengths of Niaspan™	
365			L-007 (Cefali)	ABB_SIM00683049 - ABB_SIM00683107	10/25/1995	Protocol Number 94/08 Final Report: A Three-Way Crossover Study of the Effect of Food on Niaspan™ bioavailability	
366			L-008 (Cefali)	ABB_SIM00037509 - ABB_SIM00037522	11/20/1997	Draft document sent to FDA on November 20, 1997	
367			L-009 (Cefali); SIM-200 (Toth)	N/A	01/01/1990	USP XXII, The United States Pharmacopeia (Twenty-Second Revision) (highlighted)	Lack of foundation for date description
368			L-010 (Cefali)	ABB_SIM00682575 - ABB_SIM00682577	11/17/1989	Dissolution Data for Niacin	
369			L-011 (Cefali)	ABB_SIM00682578 - ABB_SIM00682582	09/14/1995	Internal Memorandum regarding Wednesday Niaspan™ Weekly Project Meeting Minutes for September 6 and September 13	
370			L-012 (Cefali)	ABB_SIM00682583 - ABB_SIM00682587	03/19/1991	U.S. Patent No. 5,000,962	403 (cumulative), Lack of foundation for date description
371			L-013 (Cefali)	ABB_SIM00682588 - ABB_SIM00682589	03/18/1998	USPTO Declaration for Patent Application and Power of Attorney (Eugenio Cefali)	106, 403 (cumulative)
372			L-014 (Cefali)	ABB_SIM00682590 - ABB_SIM00682601	11/15/2006	Cefali, et al., *Aspirin reduces cutaneous flushing after administration of an optimized extended-release niacin formulation,* 45(2) Int. J. Clin. Pharm. Ther., pp. 78-88 (2007)	
373			L-015 (Cefali)	ABB_SIM00682602 - ABB_SIM00682603		Niaspan™ Biostudy Products	
374			L-016 (Cefali)	ABB_SIM00682604 - ABB_SIM00682754	11/07/1995	Protocol Number 95/01 Final Report: Appendix L, Analytical reports	
375			L-017 (Cefali)	ABB_SIM00682755 - ABB_SIM00682811	11/21/1995	Protocol Number 95/02 Final Report: The Comparative Bioavailability of 500mg and 1000mg Tablet Strengths of Niaspan™	
376			L-017A (Cefali)	ABB_SIM00682812 - ABB_SIM00682814		Niaspan 500mg, Quality Control Release/Rejected Form	
377			L-018 (Cefali)	ABB_SIM00682815 - ABB_SIM00682838		Kos Pharmaceuticals, Inc. NDA 20-381: Dropouts and Withdrawals	
378			L-019 (Cefali)	ABB_SIM00682839 - ABB_SIM00682845		PowerPoint Presentation: Flushing Episodes Per Patient	
379			L-020 (Bova)	ABB_SIM00682027 - ABB_SIM00682028	11/20/2008	Retainer letter from Paul Yasger to David Bova	
380			L-021 (Bova)	ABB_SIM00682029 - ABB_SIM00682105		Kos Pharmaceuticals, Inc., Labeling Supplement regarding NDA 20-381	
381			L-022 (Bova)	ABB_SIM00682106 - ABB_SIM00682109	12/03/1991	Memorandum of meeting regarding IND 34,613 Niaspan (sustained release niacin)	
382			L-026 (Bova)	ABB_SIM00682150		Kos Pharmaceuticals, Inc, NDA 20-381 Summary Table D.2 Physical Characteristics for Niaspan™ Tablets	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
383			L-027 (Bova); SIM-021 (Bova)	ABB_SIM00682151 - ABB_SIM00682180		Nicotinic Acid/Aspirin Combination: Project Proposal	
384			L-028 (Bova)	ABB_SIM00682181 - ABB_SIM00682204	12/03/1991	FDA meeting handout, Once-A-Day Niaspan for the Treatment of Type II Primary Hyperlipoproteinemia	
385			L-029 (Bova)	ABB_SIM00682205 - ABB_SIM00682208	12/05/1966	Pinter, et al., *Biphasic Nature of Blood Glucose and Free Fatty Acid Changes Following Intravenous Nicotinic Acid in Man* , Nicotinic Acid Effect on FFA (March 1967)	
386			L-030 (Bova)	ABB_SIM00682209 - ABB_SIM00682212	04/01/1977	Schlierf & Hess, Inhibition of Carbohydrate-Induced Hypertriglyceridemia by Nicotinic Acid, 3(2) Artery, pp. 174-179 (1977)	403 (cumulative), Lack of foundation for date description
387			L-031 (Bova); SIM-356 (Williams)	ABB_SIM00682213 - ABB_SIM00682224	08/11/1992	Facsimile from M. Patel regarding Kos Pharmaceuticals, Inc.'s Summary of Development Projects	
388			L-032 (Bova)	ABB_SIM00682225 - ABB_SIM00682228		Kos Pharmaceuticals, Inc. Projects Under Active Development	
389			L-033 (Bova); SIM-344 (Williams)	ABB_SIM00682229 - ABB_SIM00682264	01/01/1987	Formulating for Controlled Release with METHOCEL cellulose ethers	Lack of foundation for date description
390			L-034 (Bova)	ABB_SIM00682265 - ABB_SIM00682266		Niaspan™ Development Pharmaceutics: Relevant Studies Performed	
391			L-035 (Bova)	ABB_SIM00682267 - ABB_SIM00682270	09/13/1995	Internal Memorandum regarding Niaspan Stability Data	
392			L-036 (Bova)	ABB_SIM00682271 - ABB_SIM00682278		Physicians' Desk Reference, 4nd edition (1988): excerpts	106
393			L-037 (Tolli)	ABB_SIM00689931 - ABB_SIM00689934	06/24/2008	Email correspondence regarding GPRA Organizational Announcement	402
394			L-038 (Tolli)	ABB_SIM00689935 - ABB_SIM00689942	01/01/2008	Expectation Setting and Performance Assessment (Natalie Tolli)	Lack of foundation for date description, 402
395			L-039 (Tolli)	ABB_SIM00689943 - ABB_SIM00689956	04/20/2010	Abbott v. Lupin: Defendants' Notice of Deposition of Plaintiff Under Rule 30(b)(6)	402
396			L-040 (Tolli)	ABB_SIM00689957 - ABB_SIM22689970	04/04/2008	Email correspondence regarding Niaspan NDA submission log	
397			L-041 (Tolli)	ABB_SIM00689971 - ABB_SIM00689972	03/07/2007	Niaspan - S-023 AND S-027 - Submission Documents	
398			L-042 (Tolli)	ABB_SIM00689973 - ABB_SIM00689986	05/29/2009	Email correspondence regarding Niaspan CCDS - Request for regulatory history	802
399			L-043A (Tolli)	ABB_SIM00690038		Kos Pharmaceuticals, Inc., NDA 20-381 Prior Approval Supplement, Table of Contents	
400			L-043B (Tolli)	ABB_SIM00689987 - ABB_SIM00690012		Kos Pharmaceuticals, Inc., NDA 20-381 Prior Approval Supplement, Section 3. Summary	
401			L-043C (Tolli)	ABB_SIM00690013 - ABB_SIM00690037		Kos Pharmaceuticals, Inc., NDA 20-381 Prior Approval Supplement, Section 4. CMC	
402			L-044A (Tolli)	ABB_SIM00690039 - ABB_SIM00690044		Kos Pharmaceuticals, Inc., NDA 20-381 Prior Approval Supplement, Section 3. Summary	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
403			L-044B (Tolli)	ABB_SIM00690045 - ABB_SIM00690109		Kos Pharmaceuticals, Inc., NDA 20-381 Prior Approval Supplement, Section 4. CMC	
404			L-045 (Tolli)	ABB_SIM00690110 - ABB_SIM00690111	05/12/2009	Email correspondence regarding email correspondence for archiving	402
405			L-046 (Tolli)	ABB_SIM00690112 - ABB_SIM00690135	05/01/2009	Email correspondence regarding Niaspan Coating - Feedback required	
406			L-047 (Tolli)	ABB_SIM00690136 - ABB_SIM00690207	09/01/2006	Letter from Kos to FDA regarding Niaspan briefing documents related to IND 34,613, Serial # 0190	
407			L-048 (Tolli)	ABB_SIM00690208 - ABB_SIM00690213	05/20/2008	Email correspondence regarding confirmation of plans for long term co-back	
408			L-049 (Tolli)	ABB_SIM00690214 - ABB_SIM00690216	06/13/2008	Email correspondence regarding Niaspan LCM - Update on OTC Analysis	802
409			L-050 (Tolli)	ABB_SIM00690217 - ABB_SIM00690222	07/15/2008	Email correspondence regarding 2009 Plan - FDA User Fees	402
410			L-051 (Tolli)	ABB_SIM00690223 - ABB_SIM00690250		Abbott Laboratories, Inc., Section 3.2.P.2 Pharmaceutical Development regarding Nicotinic Acid, 375mg, 500mg, 750mg, and 1000mg prolonged release tablet	
411			L-052 (Tolli)	ABB_SIM00690251 - ABB_SIM00690259	03/01/2010	Niaspan™ Tablets Package Insert	Lack of foundation for date description
412			L-053 (Tolli)	ABB_SIM00690260 - ABB_SIM00690436	03/26/1990	Kos Pharmaceuticals, Inc., IND Application regarding Niaspan™ Reduction of elevated total and LDL cholesterol levels	106, 403 (cumulative)
413			L-054 (Tolli)	ABB_SIM00690437 - ABB_SIM00690439	08/23/1991	Kos Pharmaceuticals, Inc. letter to FDA regarding IND application 34,613 for Niaprin™	
414			L-055 (Tolli)	ABB_SIM00690440 - ABB_SIM00690456	11/26/1997	Kos Pharmaceuticals, Inc. letter to FDA regarding Niaspan® IND 34,613, Submission Serial Number 127	
415			L-056 (Tolli)	ABB_SIM00690457 - ABB_SIM00690459	06/17/1994	Kos Pharmaceuticals, Inc. letter to FDA responding to telephone conversation of June 16, 1994 concerning Niaspan™ NDA 20-381	
416			L-057 (Tolli)	ABB_SIM00690460 - ABB_SIM00690793	04/24/1996	Protocol 89/04 Final Report (Revision #1): A Single-Blind Placebo-Controlled Pilot Study Comparing the Effect of Once-a-Day Versus Twice-a-Day Dosing of Niaspan™ on Serum Lipids	
417			L-058 (Tolli)	ABB_SIM00690794 - ABB_SIM00691209	04/24/1996	Protocol 91/02 Final Report (Revision #1): A Pilot Efficacy Study of a Once-A-Day Sustained-Release Niacin Formulation (Niaspan™) in the Treatment of Primary Type IIa Hyperlipidemia	
418			L-059 (Tolli)	ABB_SIM00691210 - ABB_SIM00691369	04/25/1996	Protocol 91/04 Final Report (Revision #2): A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan™ in Patients with Primary Hyperlipoproteinemia	
419			L-060 (Tolli)	ABB_SIM00691370 - ABB_SIM00691455	04/25/1996	Protocol 91/04 Appendices: A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan™ in Patients with Primary Hyperlipoproteinemia	
420			L-061 (Tolli)	ABB_SIM00691456 - ABB_SIM00692013	04/25/1996	Protocol 91/04 Laboratory Values: A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan™ in Patients with Primary Hyperlipoproteinemia	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
421			L-062 (Tolli)	ABB_SIM00692014 - ABB_SIM00692159	04/26/1996	Protocol 91/05 Final Report (Revision #1): A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan™ in Patients with Primary Hyperlipoproteinemia - A Dose-Ranging Study	
422			L-063 (Tolli)	ABB_SIM00692160 - ABB_SIM00692471	04/26/1996	Protocol 91/05 Laboratory Values: A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan™ in Patients with Primary Hyperlipoproteinemia - A Dose-Ranging Study	
423			L-064 (Tolli)	ABB_SIM00692472 - ABB_SIM00692551	04/26/1996	Protocol 91/05 Appendices: A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan™ in Patients with Primary Hyperlipoproteinemia - A Dose-Ranging Study	
424			L-065 (Tolli)	ABB_SIM00692552 - ABB_SIM00692574		Pes-Florida, Inc., Informed Consent and Terms for Research Study Forms	106, 402
425			L-066 (Tolli)	ABB_SIM00692575 - ABB_SIM00692588		Informed Consent Forms	106, 402
426			L-067 (Tolli)	ABB_SIM00692589 - ABB_SIM00692752		Clinical Investigation Consent Forms	106, 402
427			L-068 (Tolli)	ABB_SIM00692753 - ABB_SIM00692852		Consent for Research Forms	106, 402
428			L-069 (Tolli)	ABB_SIM00692853 - ABB_SIM00692899	07/06/2000	Kos Pharmaceuticals, Inc. letter to FDA regarding submission of information regarding newly issued patent for Niaspan with enclosures	402
429			L-070 (Tolli)	ABB_SIM00692900 - ABB_SIM00693083	04/25/1994	Kos Pharmaceuticals, Inc. NDA Application regarding Niacin Sustained-Release Tablets	
430			L-071 (Tolli)	ABB_SIM00693084 - ABB_SIM00693419		Kos Pharmaceuticals, Inc. NDA 20-381, Volume Number 2.3: Chemistry, Manufacturing and Controls	
431			L-072 (Tolli)	ABB_SIM00693420 - ABB_SIM00693643	08/01/1991	Protocol 89/04 Final Report, as Presented in IND 34,613 (Amendment 008): A Single-Blind Placebo-Controlled Pilot Study Comparing the Effect of Once-a-Day Versus Twice-a-Day Dosing of Niaspan™ on Serum Lipids	Lack of foundation for date description
432			L-073 (Tolli)	ABB_SIM00693644 - ABB_SIM00693805	03/27/1994	Protocol 91/02: A Pilot Efficacy Study of a Once-A-Day Sustained-Release Niacin Formulation (Niaspan™) in the Treatment of Primary Type IIa Hyperlipidemia	
433			L-074 (Tolli)	ABB_SIM00693806 - ABB_SIM00693889	01/13/1992	Protocol 91/04 Appendices: A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan™ in Patients with Primary Hyperlipoproteinemia	
434			L-075 (Tolli)	ABB_SIM00693890 - ABB_SIM00693967	01/13/1992	Protocol 91/05 Appendices: A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan™ in Patients with Primary Hyperlipoproteinemia - A Dose-Ranging Study	
435			L-077 (Sutcliffe)	ABB_SIM00688667 - ABB_SIM00688736	03/04/2008	Dyslipidemia Franchise LRP Strategy	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
436			L-078 (Sutcliffe)	ABB_SIM00688737 - ABB_SIM00688771	05/30/2008	Niaspan Physician Insights & Opportunities	
437			L-079 (Sutcliffe)	ABB_SIM00688772 - ABB_SIM00688858		Niaspan-Based Franchise	
438			L-080 (Sutcliffe)	ABB_SIM00688859		Marianne Sutcliffe summary regarding Niaspan-Molecule	
439			L-081 (Sutcliffe)	ABB_SIM00688860 - ABB_SIM00688892	05/09/2007	2008 Plan Portfolio Optimization: Niaspan Single Brand Resource Optimization (UniBrand™)	
440			L-082 (Sutcliffe)	ABB_SIM00688893 - ABB_SIM00688913	01/30/2008	Portfolio Positioning Strategy for Lipid Products Steering Team Meeting	
441			L-083 (Sutcliffe)	ABB_SIM00688914 - ABB_SIM00688943		Niaspan-Based Franchise	
442			L-084 (Sutcliffe)	ABB_SIM00688944 - ABB_SIM00689168	06/01/2004	TriCor 145 Launch Update	Lack of foundation for date description
443			L-085 (Sutcliffe)	ABB_SIM00689169 - ABB_SIM00689205		Abbott Laboratories, Inc. Executive Summary	
444			L-086 (Sutcliffe)	ABB_SIM00689206		CD-Rom Image containing a number of spreadsheets	402
445				ABB_SIM00566798		Sales data	
446				ABB_SIM00571124		Sales data	
447				ABB_SIM00571125		Sales data	
448				ABB_SIM00571126		Sales data	
449				ABB_SIM00571127		Sales data	
450			L-087 (Sutcliffe)	ABB_SIM00689207		Niaspan P&L 2007-2009 Actuals	
451			L-088 (Sutcliffe)	ABB-SIM00689208 - ABB_SIM00689209		Sales figures	
452			L-089 (Sutcliffe); SIM-126 (Williams)	ABB_SIM00689210 - ABB_SIM00689211		Sales figures (Advicor & Simcor: 2006-2010)	
453			L-090 (Sutcliffe)	ABB_SIM00689212		Niaspan Rebate Options	
454			L-091 (Sutcliffe)	ABB_SIM00689213 - ABB_SIM00689215	06/27/2007	Email correspondence regarding "When are we going to see Niaspan move?"	
455			L-092 (Sutcliffe)	ABB_SIM00689216 - ABB_SIM00689220	08/10/2007	CPRM 2008 Clinical Budget Review Summary	402
456			L-093 (Sutcliffe)	ABB_SIM00689221 - ABB_SIM00689222		Niaspan Price Rollforward, 2009 Update Corporate Review and Dyslipidemia Channel Summary Analysis, 2009 Update Corporate Review	
457			L-094 (Sutcliffe)	ABB_SIM00689223		Kos Price Volume vs. Plan	
458			L-095 (Sutcliffe)	ABB_SIM00689224 - ABB_SIM00689233		Niaspan Sales Figures (Actuals and History)	
459			L-096 (Sutcliffe)	ABB_SIM00689234 - ABB_SIM00689241	04/16/2007	Memorandum regarding Dyslipidemia Portfolio Overview - Follow-up from LRP	
460			L-097 (Sutcliffe)	ABB_S2_02558325		Study Data	402
461			L-098 (Sutcliffe)	ABB_SIM00689242 - ABB_SIM00689263	02/01/2009	Dyslipidemia LRP Strategic Overview	Lack of foundation for date description

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
462			L-099 (Sutcliffe)	ABB_SIM00689264 - ABB_SIM00689296	10/19/2006	Acquisition Assessment Project Parthenon	
463			L-100 (Sutcliffe)	ABB_SIM00688582 - ABB_SIM00688614	01/01/2009	IMS Data	Lack of foundation for date description
464			L-101 (Sutcliffe)	ABB_SIM00688650 - ABB_SIM00688651	07/11/2008	Email correspondence regarding BARR Royalty	
465			L-103 (Sutcliffe)	ABB_SIM00688652 - ABB_SIM00688653		Xience V™ Patient Care Program	402
466			L-104 (Sutcliffe)	ABB_SIM00688654 - ABB_SIM00688661	07/13/2001	Warning letter from FDA to Kos Pharmaceuticals, Inc.	802
467			L-105 (Sutcliffe)	ABB_SIM00688662 - ABB_SIM00688666	08/26/1997	Letter from FDA to Kos Pharmaceuticals, Inc.	802, 403 (cumulative)
468			L-106 (Williams)	ABB_SIM00694197 - ABB_SIM00694241	05/01/2010	2010 Dyslipidemia Brand Planning: Market Landscape	Lack of foundation for date description
469			L-107 (Williams)	ABB_SIM00694242 - ABB_SIM00694246		Choice Summary, 1: Market Focus - Niaspan	
470			L-108 (Williams)	ABB_SIM00694247 - ABB_SIM00694297		2010 ACE Review, Niaspan	
471			L-109 (Williams)	ABB_SIM00694298 - ABB_SIM00694302		Niaspan/SIMCOR 2010 Project Plans	
472			L-110 (Williams)	ABB_SIM00694303 - ABB_SIM00694314		Dyslipidemia TRx IMS Data	
473			L-111 (Williams)	ABB_SIM00694315		Pharmaceutical Products Division, 2009 Update	
474			L-112 (Williams)	ABB_SIM00694316 - ABB_SIM00694317		Sales Figures	
475			L-112A (Williams)	ABB_SIM00694318		Niaspan 2010 Actuals	
476			L-113 (Williams)	ABB_SIM00694319 - ABB_SIM00694320		Niaspan Flushing: ASA Tapering (G0429054)	
477			L-114 (Williams)	ABB_SIM00694321 - ABB_SIM00694322	01/01/2008	Niacin Products - Margin Summary, 2009 LRP	Lack of foundation for date description
478			L-115 (Williams)	ABB_SIM00694323		CD-Rom Image "Monthly Highlights"	402
479				ABB_SIM00566768		Niaspan Highlights	
480				ABB_SIM00566773 - ABB_SIM00566775		Monthly Performance Update - Niaspan	
481				ABB_SIM00566797		Niaspan Highlights	
482			L-116 (Poulos)	ABB_SIM00685434 - ABB_SIM00685485	01/28/2004	TEC Meeting	
483			L-117 (Poulos)	ABB_SIM00685486 - ABB_SIM00685493	03/20/2006	Email correspondence regarding Licensing Projects (Current Status)	
484			L-118 (Poulos)	ABB_S2_00264399		Sales data	
485			L-118 (Poulos)	ABB_S2_00276496		Sales data	
486			L-118 (Poulos)	ABB_S2_00310274		Sales data	
487			L-118 (Poulos)	ABB_S2_00310973		Sales data	
488			L-118 (Poulos)	ABB_S2_00313610		Sales data	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
489			L-118 (Poulos)	ABB_S2_00314847		Sales data	
490			L-118 (Poulos)	ABB_S2_00314952 - ABB_S2_00314977		Sales data	
491			L-118 (Poulos)	ABB_S2_00347286		Sales data	
492			L-118 (Poulos)	ABB_S2_00891406		Sales data	
493			L-118 (Poulos)	ABB_S2_00896480		Sales data	
494			L-118 (Poulos)	ABB_S2_00890765		Sales data	
495			L-118 (Poulos)	ABB_S2_00957542		Sales data	
496			L-118 (Poulos)	ABB_S2_02349329		Sales data	
497			L-118 (Poulos)	ABB_S2_03117320		Sales data	
498			L-119 (Poulos)	ABB_SIM00685494 - ABB_SIM00685527	04/12/2005	Co-Promotion Agreement between Kos Pharmaceuticals, Inc. and Barr Laboratories, Inc.	
499			L-120 (Poulos)	ABB_SIM00685528 - ABB_SIM00685572	04/12/2005	License and Manufacturing Agreement between Kos Pharmaceuticals, Inc. and Barr Laboratories, Inc.	403 (cumulative)
500			L-121 (Poulos)	ABB_SIM00685573 - ABB_SIM00685595	04/12/2005	Settlement Agreement between Kos Pharmaceuticals, Inc. and Barr Laboratories, Inc.	403 (cumulative)
501			L-122 (Poulos)	ABB_SIM00685596 - ABB_SIM00685704	11/14/2006	Email correspondence regarding Abbott Laboratories, Tender Offer (06-23855-0)	
502			L-123 (Poulos)	ABB_SIM00685705 - ABB_SIM00685711	12/14/2006	R&D Synergy Estimation Issue Discussion	
503			L-124 (Poulos)	ABB_SIM00685712 - ABB_SIM00685715	05/08/2006	Abbott Laboratories, Inc. Pharmaceutical Licensing & New Business Development Memorandum regarding April 2006 Highlights	
504			L-125 (Poulos)	ABB_SIM00685716 - ABB_SIM00685719	10/20/2006	Email correspondence regarding Parthenon Diligence Meetings - October 24	
505			L-126 (Poulos)	ABB_SIM00685720 - ABB_SIM00685722	10/27/2006	Email correspondence regarding IP Call	
506			L-127 (Poulos)	ABB_SIM00685723 - ABB_SIM00685724		Project Parthenon Synergy Analysis Sales Figures	
507			L-128 (Poulos)	ABB_SIM00685725		Dyslipidemia Franchise Top 5 Priorities	
508			L-129 (Poulos)	ABB_SIM00685726 - ABB_SIM00685728	01/23/2007	Kos Update - January 23 2007	
509			L-130 (Poulos)	ABB_SIM00685729 - ABB_SIM00685759	01/31/2007	Kos Project Portfolio Review, Niaspan/Simcor Program	
510			L-131 (Poulos)	ABB_SIM00685760 - ABB_SIM00685763	10/02/2007	Abbott Laboratories, Inc. Pharmaceutical Licensing & New Business Development Memorandum regarding September 2007 Highlights	
511			L-132 (Poulos)	ABB_SIM00685764 - ABB_SIM00685770	07/03/2008	Abbott Laboratories, Inc. Pharmaceutical Licensing & New Business Development Memorandum regarding June 2008 Highlights	
512			L-133 (Poulos)	ABB_SIM00685771 - ABB_SIM00685808	06/01/2009	Pharmaceutical Products Group, 2009 Update, TCF Review June 1st 2009	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
513			L-134 (McGovern)	ABB_SIM00684380 - ABB_SIM00684383	08/08/1990	Garg & Grundy, *Nicotinic Acid as Therapy for Dyslipidemia in Non-Insulin-Dependent Diabetes Mellitus,* 264 JAMA, pp. 723-726 (1990)	403 (cumulative)
514			L-135 (McGovern); SIM-158 (McGovern)	ABB_SIM00684384 - ABB_SIM00684410	01/19/2007	Email correspondence regarding Coronary Drug Project - follow up to Portfolio Review	106
515			L-136 (McGovern)	ABB_SIM00684411 - ABB_SIM00684412	01/15/1997	Protocol 96/01 Final Report Abstract	106
516			L-137 (McGovern)	ABB_SIM00684413 - ABB_SIM00684676		Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III "ATP III"), Final Report	403 (cumulative)
517			L-138 (McGovern)	ABB_SIM00684677 - ABB_SIM00684710	09/28/1987	DeWitt, et al., *Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults* , 148 Arch. Intern. Med, pp. 36-69 (1988)	403 (cumulative)
518			L-139 (McGovern)	ABB_SIM00684711 - ABB_SIM00684723	01/01/2004	Grundy, et al., *Implications of Recent Clinical Trials for the National Education Program Adult Treatment Panel III Guidelines,* 110 Circulation, pp. 227-239 (2004)	Lack of foundation for date description
519			L-140 (McGovern)	ABB_SIM00684724 - ABB_SIM00684726	11/03/1999	Letter from Mark McGovern, Kos Pharmaceuticals, Inc. to Patricia O'halloran regarding Rubins, Robins, N. Engl. J. Med. 1999; 341:410-18 reference	
520			L-141 (McGovern); SIM-147 (McGovern)	ABB_SIM00684727 - ABB_SIM00684801	03/03/2007	Launch Steering Committee Meeting - Niaspan new formulation and Simcor	
521			L-142 (McGovern); SIM-146 (McGovern)	ABB_SIM00684802	12/03/1999	Letter to Sidney Smith, University of North Carolina regarding participation in summit on HDL cholesterol	
522			L-143 (McGovern)	ABB_SIM00684803 - ABB_SIM00684804	12/29/1997	Letter to Ralph Slaker, Diversified Pharmaceutical Services, Inc. regarding post-marketing experience with Niaspan	
523			L-144 (McGovern)	ABB_SIM00684805 - ABB_SIM00684806	02/16/1998	Letter to Peter McCullough, Henry Ford Health System enclosing clinical material on the Niaspan pivotal trials and hepatoxicity of slow release (SR) naicins	
524			L-145 (McGovern)	ABB_SIM00684807 - ABB_SIM00684812	09/01/1992	Squires, et al., Low-Dose, Time-Release Nicotinic Acid: Effects in Selected Patients with Low Concentrations of High-Density Lipoprotein Cholesterol, 67 Mayo Clin. Proc., pp. 855-860 (1992)	403 (cumulative), Lack of foundation for date description
525			L-146 (McGovern)	ABB_SIM00684813 - ABB_SIM00684824	10/01/1996	Pasternak, et al., Effect of Combination Therapy with Lipid-Reducing Drugs in Patients with Coronary Heart Disease and "Normal" Cholesterol Levels, 125 Ann. Intern. Med., pp. 529-540 (1996)	403 (cumulative)
526			L-147 (McGovern)	ABB_SIM00684825 - ABB_SIM00684830	3/12/2000 - 3/15/2000	Cardiology Scientific Update, A Presentation at the 49th Annual Scientific Sessions of the American College of Cardiology	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
527			L-148 (McGovern)	ABB_SIM00684831	05/26/1999	Letter to Antonio Gotto, Weill Medical College of Cornell University regarding Gotto comment on Prognostic and Therapeutic Significance of Low Levels of High-Density Lipoprotein Cholesterol in the Archives of Internal Medicine	
528			L-148A (McGover	ABB_SIM00684832	05/27/1999	Letter from Antonio Gotto, Weill Medical College of Cornell University regarding Gotto comment on Prognostic and Therapeutic Significance of Low Levels of High-Density Lipoprotein Cholesterol in the Archives of Internal Medicine	
529			L-149 (McGovern)	ABB_SIM00684833	10/29/1999	Letter to Robert Superko, Berkeley Heart Lab regarding approval from FDA for the use of Niaspan to raise HDL cholesterol	
530			L-150 (McGovern)	ABB_SIM00684834	04/30/2001	Email correspondence regarding ATP III guidelines	
531			L-151 (McGovern)	ABB_SIM00684835 - ABB_SIM00684840	08/17/1994	Keenan, *Safety and Side Effects of Sustained-Release Niacin,* 272(7) JAMA, p. 513-516 (1994)	403 (cumulative)
532			L-152 (McGovern)	ABB_SIM00684841 - ABB_SIM00684935	12/17/1998	The American Journal of Cardiology, A Symposium: New Advances in Dyslipidemia	
533			L-153 (Liu)	ABB_SIM00683394 - ABB_SIM00683395	11/17/2008	Sarah Liu 2008 Performance Assessment	402
534			L-154 (Liu)	ABB_SIM00683396 - ABB_SIM00683402	04/26/2007	2008 Strategic Planning, Niaspan	
535			L-155 (Liu)	ABB_SIM00683403 - ABB_SIM00683437	09/27/2007	Niaspan/SIMCOR Discussion	
536			L-156 (Liu)	ABB_SIM00683438	10/23/2007	Email correspondence regarding Takeda slides	
537			L-157 (Liu)	ABB_SIM00683439 - ABB_SIM00683441	05/23/2008	Email correspondence regarding Discussion with Dr. Roizen -- Summary Notes	802
538			L-158 (Liu)	ABB_SIM00683442 - ABB_SIM00683444	10/09/2008	Email correspondence regarding Meeting 10/9/08 on Jupiter Trial results	
539			L-159 (Liu)	ABB_SIM00683445 - ABB_SIM00683447	11/19/2008	Email correspondence regarding DSN Research Results Summary and Niaspan Response	
540			L-160 (Liu); SIM-306 (Smith)	ABB_SIM00683448 - ABB_SIM00683624	10/01/2003	Kos Pharmaceuticals, Inc., Advicor®/Niaspan® Awareness, Attitude, Usage, and Positioning Study	Lack of foundation for date description
541			L-161 (Liu)	ABB_SIM00683625 - ABB_SIM00683626	02/06/2007	Email correspondence regarding Kos SMAC Panel Overview	
542			L-162 (Liu)	ABB_SIM00683627 - ABB_SIM00683631	03/16/2007	Email correspondence regarding FDA letter on VAS for flushing - FDA response - did not approve the flushing tool	
543			L-163 (Liu)	ABB_SIM00683632 - ABB_SIM00683659		Maximizing Abbott's Dyslipidemia Portfolio Through Effective Positioning of Each Product	
544			L-164 (Liu)	ABB_SIM00683660 - ABB_SIM00683663	03/26/2007	Email correspondence regarding JLT UPD Slides	
545			L-165 (Liu)	ABB_SIM00683664 - ABB_SIM00683666	03/19/2007	Email correspondence regarding Niaspan Summaries	
546			L-166 (Liu)	ABB_SIM00683667		Voicecom for Primary Care Sales Force	
547			L-167 (Liu)	ABB_SIM00683668 - ABB_SIM00683673	05/08/2007	Memorandum regarding Recommendations from the 2007 AACE Diabetes Guidelines	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
548			L-168 (Liu)	ABB_SIM00683674 - ABB_SIM00683676	05/10/2007	Email correspondence regarding Niaspan UniBrand: 60 MAX Calls Scenario	
549			L-169 (Liu)	ABB_SIM00683677 - ABB_SIM00683684	06/13/2007	Dietary Supplement Niacin Impact Research, Kick-off Meeting	
550			L-170 (Liu)	ABB_SIM00683685 - ABB_SIM00683692	07/20/2007	Email correspondence regarding Update - Niaspan Qual Study with Flushing Focus	
551			L-171 (Liu)	ABB_SIM00683693 - ABB_SIM00683694	07/26/2007	Email correspondence regarding Niaspan persistency	
552			L-172 (Liu)	ABB_SIM00683695 - ABB_SIM00683698	08/05/2007	Email correspondence regarding Flushing	
553			L-173 (Liu)	ABB_SIM00683699 - ABB_SIM00683700	09/03/2007	Memorandum regarding Cordaptive Launch Preparedness Initiatives	
554			L-174 (Liu)	ABB_SIM00683701 - ABB_SIM00683705	09/05/2007	Email correspondence regarding Merck Session Notes	802
555			L-175 (Liu)	ABB_SIM00683706 - ABB_SIM00683719	09/24/2007	Niaspan RMDM Update	
556			L-176 (Liu)	ABB-SIM00683720 - ABB_SIM00683752	04/22/2009	Niaspan/SIMCOR Data for the Data Gaps for ACE	
557			L-177 (Liu)	ABB_SIM00683753 - ABB_SIM00683754	10/15/2007	Email correspondence regarding persistency & compliance data provided to Michael	1002
558			L-178 (Liu)	ABB_SIM00683755 - ABB_SIM00683757	12/04/2007	Email correspondence regarding CSM Feedback - Niaspan Flushing	
559			L-179 (Liu)	ABB_SIM00683758 - ABB_SIM00683761	12/11/2007	Email correspondence regarding Niaspan Rapid Recall Study Results	1002
560			L-180 (Liu)	ABB_SIM00683762 - ABB_SIM00683763	01/17/2008	Email correspondence regarding LRP wording	
561			L-181 (Liu)	ABB_SIM00683764 - ABB_SIM00683766	01/17/2008	Email correspondence regarding T2 Call Plan Development	
562			L-182 (Liu)	ABB_SIM00683767 - ABB_SIM00683768	02/19/2008	Niaspan Co-Pack with ASA, LTSS meeting	
563			L-183 (Liu)	ABB_SIM00683769 - ABB_SIM00683771	06/17/2008	Email correspondence regarding GMA - Dr. Oz discusses DSN	802
564			L-184 (Liu)	ABB_SIM00683772 - ABB_SIM00683778	05/23/2008	Email correspondence regarding MM grid for Marketing Mix Inputs	
565			L-185 (Liu)	ABB_SIM00683779 - ABB_SIM00683785	07/30/2008	Email correspondence regarding Dyslipidemia News 7.29.08	
566			L-186 (Liu)	ABB_SIM00683786 - ABB_SIM00683794	10/14/2008	Email correspondence regarding JUPITER Talking Points - RESENDING	802
567			L-187 (Liu)	ABB_SIM00683795 - ABB_SIM00683796	12/08/2008	Memorandum regarding Request for Proposal, Niaspan Contingency Planning Project	
568			L-188 (Liu)	ABB_SIM00683797 - ABB_SIM00684046	11/17/2008	Abbott Laboratories, Q4 2008 Dyslipidemia AAU	
569			L-189 (Liu)	ABB_SIM00684047 - ABB_SIM00684050	02/04/2009	Email correspondence regarding Material Remediation Review - Prioritized however not reviewed with broader team yet	

EXHIBIT N

DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
570			L-190 (Liu)	ABB_SIM00684051 - ABB_SIM00684072	02/19/2009	Dyslipidemia Franchise Team Meeting	
571			L-191 (Liu)	ABB_SIM00684073 - ABB_SIM00684079	03/01/2009	Niaspan Patient Type Identification Strategy	Lack of foundation for date description
572			L-192 (Liu)	ABB_SIM00684080 - ABB_SIM00684082	04/20/2009	Email correspondence regarding Arthur Agaston, MD - Niacin "Prevention Magazine" article, May 2009 issue	802, 1002
573			L-193 (Liu)	ABB_SIM00684083 - ABB_SIM00684095	05/06/2009	Niaspan Franchise Staff	
574			L-195 (McGovern)	ABB_SIM00684986 - ABB_SIM00684992	7/23/20010	Plaintiffs' Second Supplemental Objections and Responses to Lupin Pharma's First Set of Interrogatories (Nos. 1-10)	
575			L-196 (McGovern)	ABB_SIM00684993 - ABB_SIM00684997	12/01/1988	Figge, et al., Comparison of Excretion of Nicotinuric Acid After Ingestion of Two Controlled Release Nicotinic Acid Preparations in Man, 28 J. Clin. Pharmacol., pp. 1136-1140 (1988)	403 (cumulative), Lack of foundation for date description
576			L-197 (McGovern)	ABB_SIM00684998 - ABB_SIM00685000	12/02/1997	Tato, et al., *Effects of Crystalline Nicotinic Acid-Induced Hepatic Dysfunction on Serum Low-Density Lipoprotein Cholesterol and Lecithin Choleseteryl Acyl Transferase,* 81 Am. J. Cardiol., pp. 805-807 (1998)	403
577			L-198 (McGovern)	ABB_SIM00685001 - ABB_SIM00685006	08/24/2001	Kane, et al., Cholesterol and Clycemic Effects of Niaspan in Patients with Type 2 Diabetes, 21(12) Pharmacotherapy, pp. 1473-1478 (2001)	
578				ABB_SIM00533178 - ABB_SIM00533279	08/12/2003	Kos v. Barr: Deposition Transcript of Marvin Blanford	802
579				ABB_SIM00534009 - ABB_SIM00534131	08/27/2003	Kos v. Barr: Deposition Transcript of Mark McGovern	802
580				ABB_SIM00534201 - ABB_SIM00534316	09/10/2003	Kos v. Barr: Deposition Transcript of Karen Messick	802
581				ABB_SIM00533731 - ABB_SIM00533846	09/18/2003	Kos v. Barr: Deposition Transcript of Christopher Kiritsy	802
582				ABB_SIM00533072 - ABB_SIM00533177	09/24/2003	Kos v. Barr: Deposition Transcript of Daniel Bell	802
583				ABB_SIM00534470 - ABB_SIM00534575	10/7/2003	Kos v. Barr: Deposition Transcript of George Toth	802
584				ABB_SIM00564795 - ABB_SIM00564935	10/15/2003	Kos v. Barr: Deposition Transcript of Victoria O'Neill	802
585				ABB_SIM00532984 - ABB_SIM00533071	10/17/2003	Kos v. Barr: Deposition Transcript of Suzanne Balandis	802
586				ABB_SIM00540764 - ABB_SIM00540857	10/21/2003	Kos v. Barr: Deposition Transcript of Mukesh Patel	802
587			SIM-354 (Williams)	ABB_SIM00533280 - ABB-SIM00533376	10/22/2003	Kos v. Barr: Deposition Transcript of David Bova	802
588				ABB_SIM00533377 - ABB_SIM00533470	10/23/2003	Kos v. Barr: Deposition Transcript of David Bova	802
589					10/28/2003	Kos v. Barr: Deposition Transcript of Thomas Ferder	802

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
590				ABB_SIM00565621 - ABB_SIM00565708	10/29/2003	Kos v. Barr: Deposition Transcript of Kuldip Raj Malhotra	802
591					10/30/2003	Kos v. Barr: Deposition Transcript of David Kropp	802
592				ABB_SIM00533561 - ABB_SIM00533682	10/30/2003	Kos v. Barr: Deposition Transcript of Eugenio Cefali	802
593					10/30/2003	Kos v. Barr: Deposition Transcript of Kevin Lanigan	802
594				ABB_SIM00533683 - ABB_SIM00533730	11/19/2003	Kos v. Barr: Deposition Transcript of Karen DiStefano	802
595				ABB_SIM00534378 - ABB_SIM00534469	11/25/2003	Kos v. Barr: Deposition Transcript of Arthur Straughn	802
596				ABB_SIM00534132 - ABB_SIM00534200	12/03/2003	Kos v. Barr: Deposition Transcript of Mark McGovern	802
597					12/11/2003	Kos v. Barr: Deposition of Keith Greathouse	802
598				ABB_SIM00533904 - ABB_SIM00534008	12/12/2003	Kos v. Barr: Deposition Transcript of Peter Manso	802
599				ABB_SIM00534317 - ABB_SIM00534377	12/18/2003	Kos v. Barr: Deposition Transcript of Karen Messick	802
600				ABB_SIM00565581 - ABB_SIM00565620	07/13/2004	Kos v. Barr: Deposition Transcript of Victoria O'Neill	802
601				ABB_SIM00533471 - ABB_SIM00533560	03/24/2005	Kos v. Barr: Deposition Transcript of Eugenio Cefali	802
602				ABB_SIM00682305 - ABB_SIM00682571	12/10/2009	Abbott v. Lupin: Deposition Transcript of Eugenio Cefali	802
603				ABB_SIM00681653 - ABB_SIM00681998	12/17/2009	Abbott v. Lupin: Deposition Transcript of David Bova	802
604				ABB_SIM00689819 - ABB_SIM00689930	06/10/2010	Abbott v. Lupin: Deposition Transcript of Natalie Tolli	802
605				ABB_SIM00688231 - ABB_SIM00688581	06/11/2010	Abbott v. Lupin: Deposition Transcript of Marianne Sutcliffe	802
606				ABB_SIM00693968 - ABB_SIM00694196	06/17/2010	Abbott v. Lupin: Deposition Transcript of Medgar Williams	802
607				ABB_SIM00685186 - ABB_SIM00685433	06/25/2010	Abbott v. Lupin: Deposition Transcript of John Poulos	802
608				ABB_SIM00684096 - ABB_SIM00684379	07/15/2010	Abbott v. Lupin: Deposition Transcript of Mark McGovern	802
609				ABB-SIM00683129 - ABB_SIM00683393	07/23/2010	Abbott v. Lupin: Deposition Transcript of Sarah Liu	802
610				ABB_SIM00684936 - ABB_SIM00684974	08/19/2010	Abbott v. Teva: Deposition Transcript of Mark McGovern	802
611					06/20/2011	Abbott v. Teva: Deposition Transcript of David Bova	802
612			SIM-001 (Bova)	ABB_S2_00192028 - ABB_S2_00192029	12/07/1988	Letter from David Bova to Dr. Ernst Schaefer, Head, Lipid Metabolism Laboratory, USDA Laboratory at Tufts University	
613			SIM-002 (Bova)	ABB_S2_00044517 - ABB_S2_00044518	01/19/1989	Letter from David Bova to Dr. Ernst Schaefer, Head, Lipid Metabolism Laboratory, USDA Laboratory at Tufts University	403 (cumulative)

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
614			SIM-005 (Bova)	ABB_S2_00199167 - ABB_S2_00199169	Undated	Letter from David Bova, Kos Pharmaceuticals, Inc. to Dr. Schaefer	
615			SIM-009 (Bova)	ABB_S2_00068626 - ABB_S2_00068628	8/22/1989	Report on Formulation Development for NASA at MPT	802
616			SIM-012 (Bova)	ABB_S2_00044815 - ABB_S2_00044816	11/28/1989	Letter to Roger Cohn, Pat Winfield and George Toth from David Bova	
617			SIM-017 (Bova)	ABB_S3_01772869 - ABB_S3_01772887	12/03/1996	Facsimile from Valerie Ahmuty to Mike Fossler regarding Minutes of April 08, 1996 Meeting with FDA	
618			SIM-018 (Bova)	ABB_SIM00037472 - ABB_SIM00037474	04/25/1994	Letter to the FDA from David Bova regarding Original NDA Submission 20-381 for Niaspan™ (niacin) Sustained-Release Tablets for the Treatment of Primary Hyperlipoproteinemia	
619			SIM-020 (Bova)	ABB_SIM00037336 - ABB_SIM00037341	06/12/1995	Memorandum from Donald Raineri regarding Minutes of Conference Call with FDA on June 09, 1995	
620			SIM-023 (Bova)	ABB_S2_00068534 - ABB_S2_00068535	09/26/1991	Letter to Thomas Garvey from David Bova	802
621			SIM-024 (Bova)	ABB_S2_00074648 - ABB_S2_00074653	12/03/1991	Memorandum of Meeting regarding IND 34,613 NIASPAN™ (sustained release niacin)	
622			SIM-025 (Bova)	ABB_S2_00076201 - ABB_S2_00076204	08/12/1994	Memorandum to Michael Jaharis and Daniel Bell from David Bova regarding Sales of Niaspan™	
623					06/21/2011	Abbott v. Teva: Deposition Transcript of David Bova	802
624			SIM-029 (Bova)	ABB_S2_00199566 - ABB_S2_00199603	Undated	Project Proposal for Nicotinic Acid SR/Aspirin and/or Nicotinyl Alcohol Tartrate SR/Aspirin Combination	
625			SIM-030 (Bova)	ABB_S2_00044516	03/15/1989	Letter to Dr. Schaefer from David Bova	802
626			SIM-031 (Bova); SIM-355 (Williams)	ABB_SIM00677921 - ABB_SIM00677933	01/01/1988	Pharmaceutics: The Science of Dosage Form Design, Michael E. Aulton Ed. (1988)	Lack of foundation for date description
627			SIM-032 (Bova)	ABB_S2_00069519 - ABB_S2_00069523	07/03/1989	Letter to Norman Alworth from David Bova	
628					06/23/2011	Abbott v. Teva: Deposition Transcript of Eugenio Cefali	802
629			SIM-033 (Cefali)	ABB_SIM00552464 - ABB_SIM00552470	03/21/1996	Memorandum from Eugenio Cefali regarding Hypotheses concerning the relationship of niacin pharmacokinetics and clinical safety and efficacy	
630			SIM-035 (Cefali)	ABB_S2_00148933 - ABB_S2_00149008	10/15/2002	Protocol Number 94/07 Draft Report: Investigation of the Effect of Sustained-Release Niacin on Serum Transaminases and Phosphorus	
631			SIM-036 (Cefali)	ABB_SIM00566750 - ABB_SIM00566754	04/18/1996	Invention Disclosure: A controlled-release niacin input rate which manifests selected characteristics of immediate-release and sustained-release niacin	
632			SIM-037 (Cefali)	ABB_SIM00566755 - ABB_SIM00566760	04/18/1996	Invention Disclosure: Hypotheses concerning possible niacin metabolites responsible for the toxicity observed with oral niacin formulations	
633			SIM-039 (Cefali)	ABB_S2_00069736 - ABB_S2_00069737	05/30/1997	Memorandum from Eugenio Cefali regarding Why is Niaspan a better product than the sustained-release niacin products on the market?	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
634			SIM-040 (Cefali)	ABB_SIM00552452 - ABB_SIM00552453	10/22/1999	Memorandum from Eugenio Cefali regarding Slo-Niacin Competition	
635					06/24/2011	Abbott v. Teva: Deposition Transcript of Eugenio Cefali	802
636			SIM-044 (Cefali)	ABB_SIM00020228 - ABB_SIM00020287	03/29/1994	Protocol Number 91/09 Amendment Number 4: A Multi-Center, Open-Label Trial of the Long-Term Safety and Efficacy of Niaspan™ in Patients with Primary Hyperlipoproteinemia	
637			SIM-045 (Cefali)	ABB_SIM00014202 - ABB_SIM00014349	04/26/1996	Protocol Number 91/05 Final Report: A Double-Blind Placebo-Controlled Multi-Center Trial of the Safety and Efficacy of Niaspan in Patients with Primary Hyperlipoproteinemia - A Dose Ranging Study	
638			SIM-047 (Cefali)	ABB_S2_00141440 - ABB_S2_00141443	09/16/1996	Internal Memorandum from Eugenio Cefali regarding The Use of Aspirin and Nonsteroidal Anti-inflammatory Drugs (NSAIDs) to reduce niacin-induced flush	
639			SIM-048 (Cefali)	ABB_S2_00196592 - ABB_S2_00196596	11/25/1981	Wilkin, et al., *Aspirin blocks nicotinic acid-induced flushing,* 31(4) Clin. Pharmacol. Ther., pp. 478-482 (1982)	403 (cumulative)
640			SIM-049 (Cefali)		09/28/1987	DeWitt, et al., *Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults* , 148 Arch. Intern. Med, pp. 36-69 (1988)	403 (cumulative)
641			SIM-050 (Cefali)		08/16/1996	Davignon, et al., *Comparative Efficacy and Safety of Pravastatin, Nicotinic Acid and the Two Combined in Patients with Hypercholesterolemia,* 73 Am. J. Cardiol., pp. 339-345 (1994)	403 (cumulative)
642					07/08/2011	Abbott v. Teva: Deposition Transcript of Joseph Errigo	802
643			SIM-052 (Errigo)		06/28/2011	Abbott v. Teva: Subpoena to Time-Cap Labs, Inc. (for testimony)	402
644			SIM-053 (Errigo)		06/02/2011	Abbott v. Teva: Subpoena to Time-Cap Labs, Inc. (for documents)	402
645			SIM-054 (Errigo)	TC0025	09/16/1987	Department of Health and Human Services, Drug Product Listing for Sustained Release Niacin 125mg	Lack of foundation for date description
646			SIM-055 (Errigo)	TC0028	02/24/1987	Department of Health and Human Services, Drug Product Listing for Sustained Release Niacin 125mg	802, Lack of foundation for date description
647			SIM-056 (Errigo)	TC0146	04/14/2005	Time-Cap Labs, Inc., Ingredient List for Niacin Sustained Release 125mg Capsules	802
648			SIM-057 (Errigo)	TC0148	10/30/1994	Stability Data for Niacin 125mg Capsules, 100's	802, Lack of foundation for date description
649			SIM-058 (Errigo)	TC0149	10/30/1994	Stability Data for Niacin 125mg Capsules, 1000's	802, Lack of foundation for date description
650			SIM-059 (Errigo)	TC0150	04/22/2005	Stability Data for Niacin 125mg S.R. Capsules 100'S	802, Lack of foundation for date description
651			SIM-060 (Errigo)	TC0151	04/22/2005	Stability Data for Niacin 125mg S.R. Capsules 1000'S	802, Lack of foundation for date description
652			SIM-061 (Errigo)	TC0166	06/16/1988	Time-Cap Labs, Inc., Master Formula for Niacin 125mg S.R. Capsules	802

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
653			SIM-062 (Errigo)	TC0167	09/25/1986	Time-Cap Labs, Inc., Capsule Fill Record for Niacin 125mg S.R. Capsules	802
654			SIM-063 (Errigo)	TC0031	06/09/1988	Department of Health and Human Services, Drug Product Listing for Sustained Release Niacin 500mg	802, Lack of foundation for date description
655			SIM-064 (Errigo)	TC0145	07/02/2008	Time-Cap Labs, Inc., Ingredient List for Niacin Sustained Release Capsules, 500mg	802
656			SIM-065 (Errigo)	TC0074	03/12/2007	Time-Cap Labs, Inc., Product Specification for Niacin Extended Release Capsules, 500mg	802
657			SIM-066 (Errigo)	TC0076	08/19/2008	Time-Cap Labs, Inc., Certificate of Analysis for Niacin Extended Release Capsules, 500mg	802
658			SIM-067 (Errigo)	TC0158	07/05/1988	Stability Data for Niacin 500mg S.R. Capsules, 100's	802, Lack of foundation for date description
659			SIM-068 (Errigo)	TC0159	07/05/1988	Stability Data for Niacin 500mg S.R. Capsules, 1000's	802, Lack of foundation for date description
660			SIM-069 (Errigo)	TC0175	06/16/1988	Time-Cap Labs, Inc., Master Formula for Niacin 500mg S.R. Capsules	802
661			SIM-070 (Errigo)	TC0157	10/18/2004	Stability Data for Niacin 400mg S.R. Capsules, 1000's	802, Lack of foundation for date description
662			SIM-071 (Errigo)	TC0156	10/18/2004	Stability Data for Niacin 400mg S.R. Capsules, 100's	802, Lack of foundation for date description
663			SIM-072 (Errigo)	TC0077	01/22/2008	Stability Data for Niacin 250mg Extended Release Capsules, 100's	802, Lack of foundation for date description
664			SIM-073 (Errigo)	TC0078	01/22/2008	Stability Data for Niacin 250mg Extended Release Capsules, 1000's	802, Lack of foundation for date description
665			SIM-074 (Errigo)	TC0153	08/09/2010	Stability Data for Niacin 250mg Extended Release Capsules, 100's	802, Lack of foundation for date description
666			SIM-075 (Errigo)	TC0154	08/09/2010	Stability Data for Niacin 250mg Extended Release Capsules, 1000's	802, Lack of foundation for date description
667			SIM-076 (Errigo)	TC0030	02/24/1987	Department of Health and Human Services, Drug Product Listing for Sustained Release Niacin 400mg, 1000's	Lack of foundation for date description
668			SIM-077 (Errigo)	TC0027	09/16/1987	Department of Health and Human Services, Drug Product Listing for Sustained Release Niacin 400mg, 100's	802, Lack of foundation for date description
669			SIM-078 (Errigo)	TC0029	02/24/1987	Department of Health and Human Services, Drug Product Listing for Sustained Release Niacin 250mg, 1000's	802,Lack of foundation for date description
670			SIM-079 (Errigo)	TC0147	09/02/2005	Time-Cap Labs, Inc., Ingredient List for Niacin Sustained Release Capsules, 400mg	802
671			SIM-080 (Errigo)	TC0152	01/25/1987	Stability Data for Niacin 250mg Capsules, 100's	802, Lack of foundation for date description
672			SIM-081 (Errigo)	TC0155	03/31/1987	Stability Data for Niacin 400mg S.R. Capsules, 1000's	802, Lack of foundation for date description
673			SIM-082 (Errigo)	TC0162 - TC0163	06/16/1988	Time-Cap Labs, Inc., Master Formula for Niacin Stock Pellets	802
674			SIM-083 (Errigo)	TC0043 - TC0044	06/23/2010	Time-Cap Labs, Inc., Master Label Forms for Niacin Extended-Release Capsules, 250mg and 500mg	802

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
675			SIM-084 (Errigo)	TC0045 - TC0046	06/11/1999	Time-Cap Labs, Inc., Master Label Forms for Niacin Extended-Release Capsules, 250mg and 500mg, 100 Capsules	802, Lack of foundation for date description
676			SIM-085 (Errigo)	TC0047 - TC0048	06/21/1999	Time-Cap Labs, Inc., Labels for Niacin	802, Lack of foundation for date description
677			SIM-086 (Errigo)	TC0052 - TC0053	03/03/2009	Time-Cap Labs, Inc., Master Label Forms for Niacin 250mg and 500mg	802
678			SIM-087 (Errigo)	TC0054 - TC0055	08/16/2005	Time-Cap Labs, Inc., Voided Labels (Revised) for Niacin 250mg and 500mg, 100 Capsules	802, Lack of foundation for date description
679			SIM-088 (Errigo)	TC0057	11/13/2009	Time-Cap Labs, Inc., Master Label Form for Niacin-SR 250mg, 100 Capsules	802, Lack of foundation for date description
680			SIM-089 (Errigo)	TC0059 - TC0062		Time-Cap Labs, Inc., Labels for Niacin S.R.	802, Lack of foundation for date description
681			SIM-090 (Errigo)	TC0063 - TC0065		Time-Cap Labs, Inc., Labels for Niacin	802
682			SIM-091 (Errigo)	TC0066 - TC0068		Time-Cap Labs, Inc., Voided Labels (Revised) for Niacin	802, Lack of foundation for date description
683			SIM-092 (Errigo)		10/05/2004	Magnified image of Time-Cap Labs, Inc., Voided Labels (Revised) for Niacin 250mg Dietary Supplement, 100 Capsules	901, 802, 403 (cumulative)
684					07/12/2011	Abbott v. Teva: Deposition Transcript of Medgar Williams	802
685			SIM-092 (Williams)		05/27/2011	Defendants' Notice of Deposition of Medgar Williams	402
686			SIM-093 (Williams)		06/01/2011	Defendants' Notice of the Rule 30(b)(6) Deposition of Abbott Laboratories and Abbot Respiratory LLC	402
687			SIM-094 (Williams)	ABB_S3_01210438 - ABB_S3_01210570	02/09/2010	Email from Medgar E. Williams to Jay Carter and Nancy Drescher regarding Flushing Decks with attachments: Niaspan/SIMCOR Consumer Flushing Insights, and NIASPAN Consumer Flushing Message Research, January 2010	
688			SIM-095 (Williams)		12/01/2010	Niaspan® Tablets Package Insert	Lack of foundation for date description
689			SIM-096 (Williams)	ABB_S3_01349510 - ABB_S3_01349586	Undated	Document production family including PowerPoint presentations and brochures	403 (cumulative)
690			SIM-097 (Williams)	ABB_S3_01326661 - ABB_S3_01326662	11/17/2009	Email from Medgar E. Williams regarding Press release: Comparative Effect of Statins vs Niacin on MRI Measured Regression of Carotid Athersclerosis in a Randomized Clinical Trial: The NIA Plaque Study	802, 1002
691			SIM-098 (Williams)	ABB_S3_01347055 - ABB_S3_01347058	06/08/2010	Email from Medgar E. Williams regarding VA Slo Niacin Study Abstract Information	802
692			SIM-099 (Williams)		12/01/2010	Byrd, et al., *Lipid and Transaminase concentrations after formulary conversion of Niaspan to Slo-Niacin,* 67 Am. J. Health-Syst. Pharm., pp. 2038-2042 (2010)	
693			SIM-100 (Williams)	ABB_S3_01347429 - ABB_S3_01347463	06/14/2010	Email from Medgar Williams regarding action items for VA Niaspan Discussion (including attachments)	
694			SIM-101 (Williams)	ABB_S3_01939344 - ABB_S3_01939346	09/27/2010	Email from Ketki P. Cabbil regarding Kaiser Risk-share opportunity	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
695			SIM-102 (Williams)		06/19/1987	Blankenhorn, et al., *Beneficial Effects of Combined Colestipol-Niacin Therapy on Coronary Atherosclerosis and Coronary Venous Bypass Grafts,* 257(23) JAMA, pp. 3233-3240 (1987)	
696			SIM-103 (Williams)	ABB_S3_00551112	03/23/2010	Email from Sarah L. Bose regarding Slo-Niacin	802
697			SIM-104 (Williams)	ABB_S3_01757784 - ABB_S3_01757789	10/28/2009	Email from Joshua Baldwin regarding Dyslipidemia News articles (with attachments)	802, 1002
698			SIM-105 (Williams)	ABB_S3_01344614 - ABB_S3_01344625	04/22/2010	Email from Medgar Williams regarding DSN Flashcard (including family attachments)	
699			SIM-106 (Williams)	ABB_S3_00809612 - ABB_S3_00809614	03/23/2010	Email from Jonathan Silver with attachment	
700			SIM-107 (Williams)	ABB_S3_00404054 - ABB_S3_00404057	02/23/2010	Email from Lance Schoff regarding, Director of Marketing Insights, Pharmaceutical Products Division Abbott	802, 1002
701			SIM-108 (Williams)		05/26/2011	Press Release, ProQuest, Abbott Dealt Blow in Cholesterol Drug Trial (May 26, 2011) (on file with Ron Winslow)	802
702			SIM-109 (Williams)	ABB_S3_00140741 - ABB_S3_00140748	10/01/2009	PowerPoint Presentation, Leading SIMCOR	Lack of foundation for date description
703			SIM-110 (Williams)	ABB_S3_01937704 - ABB_S3_01937706	08/23/2010	Email from Stephen Hough regarding Niaspan Insights	
704			SIM-111 (Williams)	ABB_S3_00599562 - ABB_S3_00599641	06/22/2010	Email from Diane Mielnikowski regarding Response to outstanding SIMCOR MMix questions including family attachments	106
705			SIM-112 (Williams)	ABB_S3_00817850 - ABB_S3_00817851	06/06/2010	Email from Medgar Williams regarding SIMCOR Contingency Plan	
706			SIM-113 (Williams)	ABB_S3_00825415 - ABB_S3_00825417	08/26/2010	Email from Medgar Williams regarding Simcor Launch: The Good, The Bad, and The Ugly!	802
707			SIM-114 (Williams)	ABB_S3_01908623 - ABB_S3_01908624	08/21/2009	Email from Edward Bryden attaching slide entitled Niaspan Share Has Declined Since Nov '08 Due To Many Market Factors	
708			SIM-115 (Williams)	ABB_S3_01753284 - ABB_S3_01753293.012	08/05/2009	Email from Kristin Elvekrog regarding 2010 Niaspan/SIMCOR Needs by Thursday (including family attachments)	
709			SIM-116 (Williams)	ABB_S3_00795318 - ABB_S3_00795348	04/10/2009	Email from Frederick Mischler III regarding Messages for Review at 1:30 EST (12:30 CST) (including family attachments)	
710			SIM-117 (Williams)	ABB_S3_01928500 - ABB_S3_01928502	03/10/2010	Email from Lance Schoff regarding Golds my man?	
711			SIM-118 (Williams)	ABB_S3_00762808 - ABB_S3_00762827	09/07/2010	Email from Chad Bernstein regarding Niaspan DTC Evolution Concepts - Formal Feedback with family attachments	802
712			SIM-119 (Williams)		12/06/2010	Settlement Agreement - Kos Pharmaceuticals, Inc.	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
713			SIM-120 (Williams)	ABB_S2_00247188 - ABB_S2_00247198	Undated	PowerPoint Presentation, Niacin Extended Release Product Family, Niaspan®, Advicor® and Simcor™	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
714			SIM-121 (Williams)	ABB_S2_00394610 - ABB_S2_00394633	09/01/2008	PowerPoint Presentation, Primary Care Commercial Execution	Lack of foundation for date description
715			SIM-122 (Williams)	ABB_S2_01583137 - ABB_S2_01583148	12/31/2009	2010 Niaspan Brand Plan	403 (cumulative)
716			SIM-123 (Williams)	ABB_S2_02096023 - ABB_S2_02096045	03/19/2009	PowerPoint Presentation, Niaspan/SIMCOR 2009 Trends/Actions to Close the Gap	
717			SIM-124 (Williams)	ABB_S3_01674343 - ABB_S3_01674387	05/01/2010	PowerPoint Presentation, 2010 Dyslipidemia Brand Planning, Market Landscape	Lack of foundation for date description
718			SIM-125 (Williams)	ABB_S2_01960446 - ABB_S2_01960480	02/15/2008	Letter from Mary H. Parks, MD, Director, Food and Drug Administration, to David Ross, Director, Abbott Pharmaceuticals (February 15, 2008) with enclosure	
719			SIM-127 (Williams)	ABB_S3_01347192 - ABB_S3_01347198	06/09/2010	Email from Medgar Williams regarding VA Slo Niacin Study Abstract Information	802
720					07/15/2011	Abbott v. Teva: Deposition Transcript of Marianne Sutcliffe	802
721			SIM-128 (Sutcliffe)		07/11/2011	Defendants' Amended Notice of Deposition of Marianne Sutcliffe with Certificate of Service	402
722			SIM-129 (Sutcliffe)		06/01/2011	Defendants' Notice of the Rule 30(b)(6) Deposition of Abbott Laboratories and Abbot Respiratory LLC	402
723			SIM-130 (Sutcliffe)	ABB_SIM00949882 - ABB_SIM00949904	Undated	Proprietary Pharmaceuticals Division, 2011 Update Reference Package	
724			SIM-131 (Sutcliffe)	ABB_S2_00681040 - ABB_S2_00681063	Undated	Raise Regress Reduce, New Niaspan Caplets	
725			SIM-132 (Sutcliffe)	ABB_S3_01269024 - ABB_S3_01269027	06/03/2008	Email from Michael Gautsch regarding Best Practice Document (with attachment)	403 (cumulative)
726			SIM-133 (Sutcliffe)	ABB_S3_01730405 - ABB_S3_01730406	12/21/2007	Email from Sarah Liu regarding Advicor Talking Points	
727			SIM-134 (Sutcliffe)	ABB_S3_00618273 - ABB_S3_00618278	06/30/2007	Email from Marianne Sutcliffe regarding T3 Call Plan Follow-up	
728			SIM-135 (Sutcliffe)	ABB_S3_00610266 - ABB_S3_00610270	06/29/2007	Email from Lisa Castaneda regarding T3 Call Plan Follow-up	
729			SIM-136 (Sutcliffe)	ABB_S2_02606331 - ABB_S2_02606391	09/05/2007	Email from Sara Liu regarding Niaspan and Advicor 2008 Plan (with attachment)	
730			SIM-137 (Sutcliffe)	ABB_S3_01905852 - ABB_S3_01905855	02/12/2008	FDA Contact Report	802
731			SIM-138 (Sutcliffe)	ABB_S2_00255624 - ABB_S2_00255628	05/31/2007	Email from Marianne Sutcliffe regarding Niaspan ASA Co-Pack	
732			SIM-139 (Sutcliffe)	ABB_S2_00321844 - ABB_S2_00321856	10/07/2008	Marianne Sutcliffe Working Draft Niaspan/SIMCOR Presentation	
733			SIM-140 (Sutcliffe)	ABB_S2_00299825 - ABB_S2_00299826	Undated	Simcor® and Niaspan® Now on Pennsylvania State Medicaid Preferred Drug List (PDL)	
734			SIM-141 (Sutcliffe)	ABB_S2_02639278 - ABB_S2_02639293	12/04/2007	Email from Sarah Liu regarding AI Launce Meeting Presentation (with attachment)	
735			SIM-142 (Sutcliffe)	ABB_S3_01297334 - ABB_S3_01297367	07/10/2009	Email from Beth Nelles regarding SIMCOR ACE Document - DRAFT (with attachment)	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
736					07/19/2011	Abbott v. Teva: Deposition Transcript of Mark McGovern	802
739			SIM-145 (McGovern)	ABB_S2_01747244 - ABB_S2_01747276	06/08/2007	Email from Bruce Brown regarding Slide files 4-6 For Chicago Investigator meeting, June 13 (with attachments)	
740			SIM-148 (McGovern)		12/30/2008	Press Release, BioSpace, AAIPharma, Inc. and Cortria Corporation Sign Drug Delivery Deal (December 30, 2008) (on file with BioSpace.com)	402, 802
741			SIM-149 (McGovern)		08/11/2008	Press Release, Cortria, Cortria Appoints Gene Cefali, Pharm.D., Ph.D. as SVP Clinical Pharmacology & Formulation Development (August 11, 2008) (on file with Dan Grau)	402, 802
742			SIM-150 (McGovern)	ABB_S3_01347285 - ABB_S3_01347292	07/13/2001	Letter from Thomas Abrams, Director, Food and Drug Administration, to Adrain Adams, President, Kos Pharmaceuticals, Inc. (July 13, 2001)	802, 403 (cumulative)
743			SIM-151 (McGovern)	ABB_S2_01068733 - ABB_S2_01068738	10/31/2001	Fax from Andrew Haffer, Regulatory Review Officer, Food and Drug Administration, to Adrain Adams, President, Kos Pharmaceuticals, Inc. (October 31, 2001) with attachments	802
744			SIM-152 (McGovern)	ABB_S2_01068739 - ABB_S2_01068749	09/27/2001	Draft: Meeting Summary Points with attachments	802
745			SIM-153 (McGovern)	ABB_S2_00071063 - ABB_S2_00071066	Undated	Step up to proven Tolerability, Kos Pharmaceuticals, Inc.,	
746			SIM-154 (McGovern)	ABB_S2_00227053	Undated	Email from Aaron Berg regarding non-prescription niacin	802
747			SIM-155 (McGovern)	ABB_S2_00227313	01/22/2002	Letter from Marvin Blanford, Vice President, Kos Pharmaceuticals, Inc., to Robert Temple, Food and Drug Administration (January 22, 2002)	
748			SIM-156 (McGovern)	ABB_S2_00227308 - ABB_S2_00227309	04/05/2002	Letter from Marvin Blanford, Vice President, Kos Pharmaceuticals, Inc., to Robert Temple, Food and Drug Administration (April 5, 2002)	
749			SIM-157 (McGovern)	ABB_S3_01939036 - ABB_S3_01939037	Undated	Niaspan Key Market Statistics	
750			SIM-159 (McGovern)	ABB_SIM00717915 - ABB_SIM00717916	Undated	MedWatch: The FDA Medical Products Reporting Program, NIASPAN	802
751			SIM-160 (McGovern)	ABB_SIM00715337	01/05/1995	MedWatch: The FDA Medical Products Reporting Program, Niaspan® 500mg tablet - Kos Pharmaceuticals, Inc.	802
752			SIM-161 (McGovern)	ABB_SIM00715420	01/05/1995	MedWatch: The FDA Medical Products Reporting Program, Niaspan® 500mg tablet - Kos Pharmaceuticals, Inc.	802
753			SIM-162 (McGovern)	ABB_SIM00715513 - ABB_SIM00715514	01/05/1995	MedWatch: The FDA Medical Products Reporting Program, Niaspan® 500mg tablet - Kos Pharmaceuticals, Inc.	802
754			SIM-163 (McGovern)	ABB_SIM00715545	01/05/1995	MedWatch: The FDA Medical Products Reporting Program, Niaspan® tablet - Kos Pharmaceuticals, Inc.	802
755			SIM-164 (McGovern)	ABB_SIM00715561	01/05/1995	MedWatch: The FDA Medical Products Reporting Program, Niaspan® tablet - Kos Pharmaceuticals, Inc.	802
756			SIM-165 (McGovern)	ABB_S3_01720732 - ABB_S3_01720733	02/15/2007	Email from Daiva Bajorunas regarding Simcor	402
757					08/23/2011	Abbott v. Teva: Deposition Transcript of Robert Padley	802

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
758			SIM-166 (Padley)		08/05/2010	Application No. 10/444,145: Interview Summary	106, 402
759			SIM-167 (Padley)		08/30/2010	Application No. 10/444,145: Interview Summary	106, 402
760			SIM-168 (Padley)		11/24/2009	Application No. 10/444, 145: Response to June 24, 2009 Office Action	106, 402
761			SIM-169 (Padley)	ABB_S3_00356068 - ABB_S3_00356089	Undated	Niacin ER/Simvastatin Tablets, 3.2.P.1 Description and Composition of Niacin ER/Simvastatin Tablet, 1000mg DC/20mg	
762			SIM-170 (Padley)	ABB_S2_00938651 - ABB_S2_00938653	07/31/2008	Email from Robert Padley regarding Thanks for yesterday and a question for next week	
763			SIM-171 (Padley)	ABB_S2_00945297 - ABB_S2_00945298	09/21/2007	Email from Robert Padley regarding Niaspan PK	
764			SIM-172 (Padley)	ABB_S2_00947151 - ABB_S2_00947154	03/16/2009	Email from Robert Padley regarding M10-592 (Simcor NS 1000DC/20 vs 1000WG/20): Preliminary Results	
765			SIM-173 (Padley)	ABB_S2_01253102 - ABB_S2_01253114	11/01/2007	Draft letter from Natalie Tolli, Associate Director, Abbott Pharmaceuticals, Inc., to Dr. Mary Parks, Division Director, Food and Drug Administration (November 1, 2007)	
766			SIM-174 (Padley)	ABB_S2_03294546 - ABB_S2_03294548	08/05/2008	Eagle/Sirius JDC Meeting Minutes	
767			SIM-175 (Padley)	ABB_S2_00251747 - ABB_S2_00251779	08/17/2007	Niaspan-based LCM	
768			SIM-176 (Padley)	ABB_S3_00822501 - ABB_S3_00822502	08/01/2010	FDA Approves New Simcor 40-mg Strengths	Lack of foundation for date description
769			SIM-177 (Padley)	ABB_S3_00551101 - ABB_S3_00551107	03/19/2010	Email from Thao Doan regarding Niaspan question - Endur-acin	
770			SIM-178 (Padley)	ABB_S3_01552058 - ABB_S3_01552066	03/08/2010	Email from Robert Padley regarding Niaspan question	802
771			SIM-179 (Padley)	ABB_S3_01581035 - ABB_S3_01581041	06/09/2010	Email from Robert Padley regarding VA Slo Niacin Study Abstract Information	802, 403 (cumulative)
772			SIM-180 (Padley)	ABB_S3_01934461 - ABB_S3_01934462	06/10/2010	Email from Robert Padley regarding USA TODAY article on supplements	403
773			SIM-181 (Padley)	ABB_S3_01934503 - ABB_S3_01934507	06/11/2010	Email from Sarah Bose regarding USA TODAY article on supplements	
774			SIM-182 (Padley)	ABB_S3_01938600 - ABB_S3_01938603	09/10/2010	Email from Jeffrey Cercy regarding Update VISN List where Niaspan Switching is occurring	802
775			SIM-183 (Padley)	ABB_S3_00762312 - ABB_S3_00762321	03/01/2010	SLO-NIACIN® Frequently Asked Questions, VHA Pharmacy Benefits Management Services, the Medical Advisory Panel and the VISN Pharmacist Executives	802, Lack of foundation for date description
776			SIM-184 (Padley)	ABB_S3_00090161 - ABB_S3_00090186	07/11/2008	Cumulative Review of Niaspan and Hepatobiliary Disorders, Review Period: 28 July 1997 through 08 April 2008, Postmarketing Safety Evaluation, 11 July 2008	
777			SIM-185 (Padley)	ABB_S3_01896877 - ABB_S3_01896880	09/24/2009	Average Value of a Niaspan Patient	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
778			SIM-186 (Padley)	ABB_S3_01949027 - ABB_S3_01949031	02/18/2009	Niaspan Simcor CPT Meeting Minutes, Final	
779			SIM-187 (Padley)		06/02/2005	United states Patent Application Publication, US 2005/0118257 A1	402
780			SIM-188 (Padley)		03/01/2010	Declaration of Frank Sacks in Support of Plaintiffs' Opening Claim Construction Brief, Abbott Laboratories, et al., v. Lupin Limited, et al., C.A. No. 09-152-JJF	802, 403 (cumulative)
781			SIM-189 (Padley)	ABB_S2_00353444 - ABB_S2_00353454	01/01/2009	Thakkar, et al., *Acetylsalicylic Acid Reduces Niacin Extended-Release-Induced Flushing in Patients with Dyslipidemia,* 9(2) Am. J. Cardiovasc Drugs, pp. 69-79 (2009)	Lack of foundation for date description
782			SIM-190 (Padley)	ABB_S3_00762425 - ABB_S3_00762430	06/21/2005	VA initiative to switch Niaspan to Slo-Niacin (a dietary supplement)	802
783			SIM-191 (Padley)	ABB_SIM01259595 - ABB_SIM01259599	Undated	Sales Force Frequently Asked Questions	
784					08/25/2011	Abbott v. Teva: Deposition Transcript of George Toth	802
785			SIM-192	N/A	08/15/2011	Defendants' Notice of Deposition of George Toth	402
786			SIM-194	ABB_SIM00562135 - ABB_SIM00562148	04/08/1998	Fax from Roger Cohn to George Toth regarding Early Niaspan	
787			SIM-197	ABB_SIM00551705 - ABB_SIM00551708	07/14/1997	Internal memorandum regarding F2 Criteria of the Production Lots	403 (cumulative)
788			SIM-199	ABB-S 00041953 - ABB-S 00041972	01/25/2000	Kos Report No.: PESR000001-1, the Effects of pH on the In-Vitro Dissolution of Niaspan® 500 and 1000-mg Tablets - SUPAC Level 2 Support for Implementation of the Littleford FM 300 High Shear Granulator	
789			SIM-201	ABB_SIM00952120 - ABB_SIM00952218	02/13/1991 - 08/20/1991	Kos Pharmaceuticals, Inc. Laboratory Notebook No. 010, Chemist: George M. Toth	
790					06/21/2011	Abbott v. Sun: Deposition Transcript of David Bova	802
791			SUN-001 (Bova)		06/17/2011	Plaintiffs Abbott Laboratories and Abbott Respiratory LLC's Responses and Objections to Defendants Sun Pharmaceutical Industries, Ltd. and Sun Pharma Global FZE's Rule 30(b)(6) Notice of Deposition	402
792			SUN-002 (Bova)		06/27/2000	U.S. Patent No. 6,080,428	403 (cumulative), Lack of foundation for date description
793			SUN-003 (Bova)		01/19/1989	Letter to Dr. Schaefer from David Bova	403 (cumulative)
794					06/24/2011	Abbott v. Sun: Deposition Transcript of Eugenio Cefali	802
795			SUN-004 (Cefali)		10/22/2002	U.S. Patent No. 6,469,035	403 (cumulative), Lack of foundation for date description
796					07/19/2011	Abbott v. Sun: Deposition Transcript of Mark McGovern	802
797			SUN-005 (McGovern)		06/17/2011	Plaintiffs Abbott Laboratories and Abbott Respiratory LLC's Responses and Objections to Defendants Sun Pharmaceutical Industries, Ltd. and Sun Pharma Global FZE's Rule 30(b)(6) Notice of Deposition	402

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
798			SUN-006 (McGovern)		Undated	Kos Pharmaceuticals, Inc., Projected Revenue for Niaspan™	
799					08/01/2011	Curriculum Vitae, William Frederick Elmquist	Lack of foundation for date description
800					08/19/2011	Attachment A to Dr. Elmquist's Opening Expert Report	802, 901, 1002, D
801					08/19/2011	Attachment B to Dr. Elmquist's Opening Expert Report	802, 901, 1002, D
802			SIM-216 (Bottorff)		08/19/2011	Attachment C to Dr. Elmquist's Opening Expert Report	802, 901, 1002, D
803			SIM-217 (Bottorff)		08/19/2011	Attachment D to Dr. Elmquist's Opening Expert Report	802, 901, 1002, D
804					08/19/2011	Attachment E-1 to Dr. Elmquist's Opening Expert Report	802, 901, 1002, D
805					08/19/2011	Attachment E-2 to Dr. Elmquist's Opening Expert Report	802, 901, 1002, D
806					08/19/2011	Attachment F to Dr. Elmquist's Opening Expert Report	802, 901, 1002, D
807					08/19/2011	Attachment G to Dr. Elmquist's Opening Expert Report	802, 901, 1002, D
808					08/19/2011	Attachment H to Dr. Elmquist's Opening Expert Report	802, 901, 1002, D
809					08/19/2011	Attachment I to Dr. Elmquist's Opening Expert Report	802, 901, 1002, D
810					08/19/2011	Attachment J to Dr. Elmquist's Opening Expert Report	802, 901, 1002, D
811					08/19/2011	Attachment K to Dr. Elmquist's Opening Expert Report	802, 901, 1002, D
812					08/19/2011	Attachment L to Dr. Elmquist's Opening Expert Report	802, 901, 1002, D
813			SIM-341 (Williams)	TV0044369 - TV0044377	06/30/1992	U.S. Patent No. 5,126,145 (Evenstad Patent)	Lack of foundation for date description
814				TV0044378 - TV0044385	12/07/1993	U.S. Patent No. 5,268,181 (O'Neill Patent)	Lack of foundation for date description
815					12/04/1992	Physicians' Desk Reference, 47th edition (1993): excerpts for Slo-Niacin	
816				USLT000075	03/30/1992	Label Copy Information regarding Slo-Niacin 500mg Tablet	802, 106
817				USLT000081	04/08/1992	Carton Copy Information regarding Slo-Niacin 500mg Tablet	802
818				USLT000084	04/08/1992	Insert Copy Information regarding Slo-Niacin 500mg Tablet	802
819			SIM-371 (Sacks)	USLT000093	07/10/1992	Carton Copy Information regarding Slo-Niacin 500mg Tablet	802
820				USLT000179	04/07/1992	Insert Copy Information regarding Slo-Niacin 750mg Tablet	802
821				USLT000266	04/14/1992	Insert Copy Information regarding Slo-Niacin 250mg Tablet	802
822				USLT000172	04/08/1992	Label Copy Information regarding Slo-Niacin 750mg Tablet	802
823				USLT000174	04/10/1992	Carton Copy Information regarding Slo-Niacin 750mg Tablet	802
824				TV0044351 - TV0044368	03/22/1995	EP 0 643 965 A1	Lack of foundation for date description
825			SIM-335 (Williams)		12/12/1991	Physicians' Desk Reference, 46th edition (1992): excerpts for Nicobid, Rebound on January 8, 1993	106
826				ABB_SIM00009066 - ABB_SIM00009400	12/01/1995	Protocol Number 91/19 Final Report Addendum: A Multiple-Dose, Cross-Over Study of the Steady-State Pharmacokinetics and Urinary Excretion of Niacin and its Major Metabolites from Niaspan™ in Reference to an Immediate-Release Formulation	Lack of foundation for date description

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
827				ABB_S2_00789385 - ABB_S2_00789460	01/15/1997	Protocol Number 96/01 Final Report: The Comparative Bioavailability of Two Sustained-Release Niacin Products Relative to Niaspan®	
828			SIM-211 (Bottorff)		04/15/2007	Stern, *The role of nicotinic acid metabolites in flushing and hepatotoxicity,* 1 J. Clin. Lipidology, pp. 191-193 (2007)	
829					08/11/2010	Belo, et al., *Hepatoprotective treatment attenuates oxidative damages induced by carbon tetrachloride in rats,* Experimental and Toxicologic Pathology (2010)	
830					05/04/2010	Sternak, et al., *Nicotinamide N-methyltransferase (NNMT) and 1-methylnicotinamide (MNA) in experimental hepatitis induced by concanavalin A in the mouse,* 62 Pharm. Reports., pp. 482-493 (2010)	
831					01/10/2010	Damian, *Photoprotective effects of nicotinamide,* 9 Photochem. Photobiol. Sci., pp. 578-585 (2010)	
832			SIM-210 (Bottorff)		03/20/2004	Gale, *European Nicotinamide Diabetes Intervention Trial (ENDIT): A randomised controlled trial of intervention before the onset of type 1 diabetes,* 363 The Lancet, pp. 925-931 (2004)	
833				TV0000342 - TV0000428	Undated	Teva Pharmaceuticals USA, 1000/20mg ANDA Section 2.7, Clinical Summary	
834			SIM-352 (Williams)	USLT000689 - USLT000710	01/04/1995	Butler Pharmapac Formula Master, Slo-Niacin Granulation	802
835					01/01/2006	Vita, Joseph Michael Keenan M.D.	Lack of foundation for date description
836				TV0044185 - TV0044194	11/14/1990	Keenan, et al., *A Randomized, Controlled Trial of Wax-Matrix Sustained-Release Niacin in Hypercholesterolemia,* 151 Arch. Intern. Med., pp. 1424-1432 (1991)	
837					06/06/1986	Canner, et al., *Fifteen Year Mortality in Coronary Drug Project Patients: Long-Term Benefit with Niacin,* 8(6) JACC, pp. 1245-1255 (1986)	
838				TV0044281 - TV0044315	09/28/1987	DeWitt, et al., *Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults* , 148 Arch. Intern. Med, pp. 36-69 (1988)	403 (cumulative)
839					11/25/1981	Wilkin, et al., *Aspirin blocks nicotinic acid-induced flushing,* 31(4) Clin. Pharmacol. Ther., pp. 478-482 (1982)	403 (cumulative)
840				TV0044205 - TV0044209	12/16/1991	Lavie, et al., *Marked Benefit with Sustained-Release Naicin Therapy in Patients with "Isolated" Very Low Levels of High-Density Lipoprotein Cholesterol and Coronary Artery Disease,* 69 Am. J. Cardiol., pp. 1083-1085 (1992)	403 (cumulative)
841				TV0044157 - TV0044164	08/16/1996	Davignon, et al., Comparative Efficacy and Safety of Pravastatin, Nicotinic Acid and the Two Combined in Patients with Hypercholesterolemia, 73 Am. J. Cardiol., pp. 339-345 (1994)	403 (cumulative)

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
842				TV0044232 - TV0044244	10/01/1996	Pasternak, et al., *Effect of Combination Therapy with Lipid-Reducing Drugs in Patients with Coronary Heart Disease and "Normal" Cholesterol Levels,* 125 Ann. Intern. Med., pp. 529-540 (1996)	403 (cumulative)
843			SIM-227 (Bottorff)	TV0145096 - TV0145110	04/26/2006	Knopp, et al., *The SLIM study: Slo-Niacin ® and Atorvastatin Treatment of Lipoproteins and Inflammatory Markers in Combined Hyperlipidemia,* 3 J. Clin. Lipid., pp. 167-178 (2009)	
844				TV0044171 - TV0044176	05/28/1996	Gardner, et al., *Combination Therapy with Low-Dose Lovastatin and Niacin Is as Effective as Higher-Dose Lovastatin,* 16(3) Pharmacotherapy, pp. 419-423 (1996)	
845			SIM-370 (Sacks)	TV0145088 - TV0145095	11/14/1991	Keenan, et al., *A Clinical Trial of Oat Bran and Niacin in the Treatment of Hyperlipidemia,* 34(3) J. Fam. Pract., pp. 313-319 (1992)	
846					12/04/1992	Physicians' Desk Reference, 47th edition (1993): excerpts for Nicobid	106, 403 (cumulative)
847					08/08/2011	Abbott v. Teva: Declaration of Terry Hammerschmidt with exhibits	802
848					08/18/2011	Vitamin and Mineral Recommendations, Council for Responsible Nutrition http://www.crnusa.org/about_recs.html	802
849			SIM-225 (Bottorff)	TV0044177 - TV0044184	08/15/1994	Gray, et al., Efficacy and Safety of Controlled-Release Niacin in Dyslipoproteinemic Veterans, 121 Ann. Intern. Med., pp. 252-258 (1994)	403
850				TV0145128 - TV0145134	09/01/1992	Squires, et al., Low-Dose, Time-Release Nicotinic Acid: Effects in Selected Patients with Low Concentrations of High-Density Lipoprotein Cholesterol, 67 Mayo Clin. Proc., pp. 855-860 (1992)	403 (cumulative), Lack of foundation for date description
851				TV0145074 - TV0145080	06/26/1989	Alderman, et al., *Effect of a Modified, Well-Tolerated Niacin Regimen on Serum Total Cholesterol, High Density Lipoprotein Cholesterol and the Cholesterol to High Density Lipoprotein Ration,* 64 Am. J. Cardiol., pp. 725-729 (1989)	
852				TV0044210 - TV0044213	06/30/1988	Luria, *Effect of Low-Dose Niacin on High-Density Lipoprotein Cholesterol and Total Cholesterol/High-Density Lipoprotein Cholesterol Ratio,* 148 Arch. Intern. Med., pp. 2493-2495 (1988)	
853					01/01/1988	Physicians' Desk Reference (42nd ed. 1988): Niaplus™, p. 2107	106, Lack of foundation for date description
854					01/01/1989	Physicians' Desk Reference (43rd ed. 1989): Niaplus™, p. 2146	106, Lack of foundation for date description
855					01/01/1989	Physicians' Desk Reference (44th ed. 1990): Niaplus™, p. 2207	106, Lack of foundation for date description
856			SIM-0375 (Sacks)	ABB_SIM01233743 - ABB_SIM01233751	04/22/1991	Dalton, et al., *Hepatotoxicity Associated with Sustained-Release Niacin,* 93 Am. J. Med., pp. 102-104 (1992)	
857					08/26/1961	Christensen, et al., *Nicotinic Acid Treatment of Hypercholesteremia,* 177(8) JAMA, PP. 546-550 (1961)	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
858				TV0044316 - TV0044325	08/04/1972	Schlierf & Dorow, *Diurnal Patters of Triglycerides, Free Fatty Acids, Blood Sugar, and Insulin during Carbohydrate-Induction in Man and Their Modification by Nocturnal Suppression of Lipolysis,* 52 J. Clin. Invest., pp. 732-740 (1973)	
859				TV0145120 - TV0145127	04/01/1977	Schlierf & Hess, *Inhibition of Carbohydrate-Induced Hypertriglyceridemia by Nicotinic Acid,* 3(2) Artery, pp. 174-179 (1977)	403 (cumulative), Lack of foundation for date description
860				TV0145111 - TV0145119	03/01/1982	Miettinen, *Diurnal variation of cholesterol precursors squalene and methyl sterols in human plasma lipoproteins,* 23 J. Lipid. Res., pp. 466-473 (1982)	Lack of foundation for date description
861					09/20/1993	08/124,392 Patent Application	
862				ABB_SIM00025287 - ABB_SIM00025705	04/24/1996	Protocol Number 91/02 Final Report: A Pilot Efficacy Study of a Once-A-Day Sustained-Release Niacin Formulation (Niaspan™) in the Treatment of Primary Type IIa Hyperlipidemia	
863					06/08/2011	Simcor Package Insert	403 (cumulative)
864					01/24/2011	Advicor Package Insert	
865				ABB_S2_00043357 - ABB_S2_00043802	02/14/2000	Protocol Number 91/09 Annual Report: A Multi-Center Open-Label Trial of the Long-Term Safety and Efficacy of Niaspan in Patients with Primary Hyperlipidemia	
866					08/17/1994	Keenan, *Safety and Side Effects of Sustained-Release Niacin,* 272(7) JAMA, p. 513 (1994)	403 (cumulative)
867					03/01/2010	Abbott v. Lupin: Declaration of Frank Sacks in Support of Plaintiffs' Opening Claim Construction Brief	403 (cumulative), 802
868					04/27/1998	Guyton, et al., *Effectiveness of Once-Nightly Dosing of Extended-Release Niacin Alone and in Combination for Hypercholeseterolemia,* 82 Am. J. Cardiol., pp. 737-743 (1998)	
869					05/09/1989	Carlson, et al., *Pronounced lowering of serum levels on lipoprotein Lp(a) in hyperlipidaemic subjects treated with nicotinic acid,* 226 J. Int. Med., pp. 271-276 (1989)	
870					07/25/1994	Illingworth, et al., *Comparative Effects of Lovastatin and Niacin in Primary Hypercholeseterolemia,* 154 Arch. Intern. Med., pp. 1586-1595 (1994)	
871					03/13/1997	Brown, et al., *Moderate Dose, Three-Drug Therapy with Niacin, Lovastatin, and Colestipol to Reduce Low-Density Lipoprotein Cholesterol <100 mg/dl in Patients with Hyperlipidemia and Coronary Artery Disease* , 80 Am. J. Cardio., pp. 111-115 (1997)	403 (cumulative)
872					08/30/1988	Gordon, et al., *High-Density Lipoprotein Cholesterol and Cardiovascular Disease, Four Prospective American Studies,* 79 Circulation, pp. 8-15 (1989)	
873				TV0044214 - TV0044223	01/01/1996	Morgan, et al., Treatment Effect of Niaspan, a Controlled-release Niacin, in Patients With Hypercholesterolemia: A Placebo-controlled Trial, 1(3) J. Cardiovasc. Pharmacol. Therapeut., pp. 195-202 (1996)	403 (cumulative), Lack of foundation for date description

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
874					01/21/2011	Abbott v. Teva: Plaintiffs' Proposed Claim Terms for Construction and Proposed Constructions	
875				TV0044165 - TV0044170	12/01/1988	Figge, et al., *Comparison of Excretion of Nicotinuric Acid After Ingestion of Two Controlled Release Nicotinic Acid Preparations in Man,* 28 J. Clin. Pharmacol., pp. 1136-1140 (1988)	403 (cumulative), Lack of foundation for date description
876				TV0044326 - TV0044337	01/01/1996	Stein, et al., *Efficacy and Tolerability of Low-dose Simvastatin and Niacin, Alone and in Combination, in Patients With Combined Hyperlipidemia: A Prospective Trial,* 1(2) J. Cardiovasc. Pharmacol. Therapeut., pp. 107-116 (1996)	Lack of foundation for date description
877				TV0044346 - TV0044350	09/24/1991	Whelan, et al., *The Effect of Aspirin on Niacin-Induced Cutaneous Reactions,* 34(2) J. Fam. Pract., pp. 165-168 (1992)	
878				TV0044386 - TV0044394	06/30/1998	U.S. Patent No. 5,773,453	403 (cumulative), Lack of foundation for date description
879				TV0044226 - TV0044231	09/01/1995	O'Keefe, et al., *Effects of Pravastatin With Niacin or Magnesium on Lipid Levels and Postprandial Lipemia,* 76 Am. J. Cardiol., pp. 480-484 (1995)	
880				TV0044395 - TV0044399	11/09/1993	U.S. Patent No. 5,260,305	Lack of foundation for date description
881					04/19/1995	Simvastatin Package Insert	
882					12/19/1991	Lovastatin Package Insert	
883					02/01/1991	Saito, et al., *Comparison Between Morning and Evening Doses of Simvastatin in Hyperlipidemic Subjects, A Double Blind Comparative Study,* 11 Arteriosclerosis and Thrombosis, pp. 816-826 (1991)	Lack of foundation for date description
884					06/08/2011	FDA Drug Safety Communication: New restrictions, contraindications, and dose limitations for Zocor (simvastatin) to reduce the risk of muscle injury http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm	
885					06/08/2011	Simvastatin Package Insert	
886					08/19/2011	Curriculum Vita, Michael B. Maurin, R.Ph., Ph.D.	
887					08/19/2011	Chart A to Dr. Maurin's Opening Expert Report	802, 901, 1002, D
888			SIM-360 (Williams)		08/19/2011	Chart B to Dr. Maurin's Opening Expert Report	802, 901, 1002, D
889			SIM-345 (Williams)		08/19/2011	Chart C to Dr. Maurin's Opening Expert Report	802, 901, 1002, D
890			SIM-346 (Williams)		08/19/2011	Chart D to Dr. Maurin's Opening Expert Report	802, 901, 1002, D
891			SIM-213 (Bottorff)		08/19/2011	Chart E to Dr. Maurin's Opening Expert Report	802, 901, 1002, D
892			SIM-348 (Williams)		08/19/2011	Chart F to Dr. Maurin's Opening Expert Report	802, 901, 1002, D

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
893			SIM-347 (Williams)		08/19/2011	Chart G to Dr. Maurin's Opening Expert Report	802, 901, 1002, D
894			SIM-349 (Williams)		08/19/2011	Chart G to Dr. Maurin's Opening Expert Report	802, 901, 1002, D
895					11/01/1963	Swintosky, *Development and Design of Oral Sustained Release Dosage Forms,* Indian J. Pharm., pp. 360-367 (1963)	Lack of foundation for date description
896				TV0145047 - TV0145054	01/18/1983	U.S. Patent No. 4,369,172	Lack of foundation for date description
897				TV0145055 - TV0145066	06/21/1983	U.S. Patent No. 4,389,393	Lack of foundation for date description
898					01/01/1985	Joseph P. Remington's Pharmaceutical Sciences, pp. 1015-1016 (1985)	Lack of foundation for date description
899					01/01/1989	The Merck Index, Eleventh Edition, pp. 1030-1031 (1989)	Lack of foundation for date description
900					03/19/1992	U.S. Patent No. 5,000,962	403 (cumulative), Lack of foundation for date description
901					01/01/1985	Joseph P. Remington's Pharmaceutical Sciences, p. 862 (1985)	Lack of foundation for date description
902				TV0008975 - TV0008989	02/26/1999	USPTO Response After Final regarding Serial No. 08/368,378	106
903					01/01/1989	The Merck Index, Eleventh Edition, pp. 1461-1462 (1989)	Lack of foundation for date description
904					01/01/1986	Handbook of Pharmaceutical Excipients: Povidone (1986)	Lack of foundation for date description
905					01/01/1986	Handbook of Pharmaceutical Excipients: Magnesium Stearate (1986)	Lack of foundation for date description
906					01/01/1986	Handbook of Pharmaceutical Excipients: Stearic Acid (1986)	Lack of foundation for date description
907				ABB_S2_00073594 - ABB_S2_00073595	12/11/1997	Meeting Minutes	802
908				ABB_S3_01880899 - ABB_S3_ 1880906	03/31/2006	Protocol Number 016-03-05-CP Final Report: The Comparative Bioequivalence of Reformulated 1000mg Extended-Release Niacin™ Tablets versus 1000mg Niaspan Tablets Administered as a Single 2000mg Dose to Healthy Volunteers	106
909				ABB_S3_01882022 - ABB_S3_01882029		Protocol Number 016-03-05-CP Final Report: Appendix L (excerpt)	106
910					09/19/2011	Attachment M-1 to Dr. Elmquist's Rebuttal Expert Report	802, 901, 1002, D
911					09/19/2011	Attachment M-2 to Dr. Elmquist's Rebuttal Expert Report	802, 901, 1002, D
912					09/19/2011	Attachment M-3 to Dr. Elmquist's Rebuttal Expert Report	802, 901, 1002, D
913					09/19/2011	Attachment N to Dr. Elmquist's Rebuttal Expert Report	802, 901, 1002, D
914					09/19/2011	Attachment O-1 to Dr. Elmquist's Rebuttal Expert Report	802, 901, 1002, D
915					09/19/2011	Attachment O-2 to Dr. Elmquist's Rebuttal Expert Report	802, 901, 1002, D

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
916				TV0145422 - TV0145445		Teva Pharmaceuticals USA, 1000/40mg ANDA Section 2.7, Clinical Summary	
917				ABB_SIM00296265 - ABB_SIM00296339		Kos Pharmaceuticals, Inc., NDA Section 2.7.1, Summary of Biopharmaceutic Studies and Associated Analytical Methods	
918				TV0023302 - TV0023341		Teva Pharmaceuticals USA, 500/20mg ANDA Section 2.7, Clinical Summary	
919				ABB_SIM00077051 - ABB_SIM00077077		Kos Pharmaceuticals, Inc., NDA Section 2.7.1, Summary of Biopharmaceutic Studies and Associated Analytical Methods	
920				TV0004575 - TV0004593		Teva Pharmaceuticals USA, 750/20mg ANDA Section 2.7, Clinical Summary	
921				WT0000416 - WT0000417		Watson Laboratories, Inc. - Florida, 1000/20mg ANDA Section 2.7.1.3, Comparison and Analysis of Results Across Studies Tables 3.3 and 3.4	
922				WT0000335 - WT0000348		Watson Laboratories, Inc. - Florida, 1000/20mg ANDA Section 2.7.1.1, Background and Overview	
923				OCA000440		Watson Laboratories, Inc. - Florida, 1000/80mg (2 x500/40mg) ANDA Section 2.7.1.3, Comparison and Analysis of Results Across Studies Table 3.1.1	
924				OCA000385 - OCA000394		Watson Laboratories, Inc. - Florida, 500/40mg ANDA Section 2.7.1.1, Background and Overview	
925				WT0000398		Watson Laboratories, Inc. - Florida, ANDA Section 2.7.1.3, Comparison and Analysis of Results Across Studies Table 2	
926				WT0000402		Watson Laboratories, Inc. - Florida, ANDA Section 2.7.1.3, Comparison and Analysis of Results Across Studies Table 2.2.1	
927				ABB_SIM00004694 - ABB_SIM00005044	12/01/1995	Protocol Number 91/18 Final Report Addendum: A Single-Dose, Crossover Study of the Pharmacokinetics and Urinary Excretion of Niacin and its Major Metabolites from Niaspan in Reference to an Immediate-Release Formulation	Lack of foundation for date description
928			SIM-220 (Bottorff)	ABB_SIM00005045 - ABB_SIM00005420	11/27/1995	Protocol Number 94/09 Final Report: The Comparative Bioavailability of 500mg and 750mg Tablet Strengths of Niaspan™	
929				ABB_SIM00007030 - ABB_SIM00007413	04/10/1996	Protocol Number 95/06 Final Report Addendum: The Comparative Bioavailability of Niaspan™ Tablets from Three Manufacturing Lots	
930				ABB_S2_03450300		M10-414 Clinical Study Report	
931				ABB_SIM00008489 - ABB_SIM00008814	10/25/1995	Protocol Number 94/08 Final Report: A Three-Way Crossover Study of the Effect of Food on Niaspan™ Bioavailability	
932				ABB_SIM00081555 - ABB_SIM00081613	11/14/2006	Clinical Study Report: 019-03-04-CP	
933				ABB_S3_00714776 - ABB_S3_00714853	01/30/2007	Final Clinical Study Report: 019-02-03-CR	
934				ABB_S3_00203800 - ABB_S3_00203911		M10-592 Clinical Study Report	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
935				TV0212076 - TV0212107	06/01/2011	Simcor® Package Insert	403 (cumulative), Lack of foundation for date description
936				OCA000146		Watson Laboratories, Inc. - Florida, ANDA Section 1.14.1.3, Draft Labeling Text	
937				ABB_SIM00324835 - ABB_SIM00324887	11/24/2009	Periodic Report	
938				ABB_SIM00733963 - ABB_SIM00734030	11/16/2010	Periodic Report	
939				ABB_S2_00535914	01/18/2007	Kos Life Sciences, Seacoast Study	106
940					06/01/2011	FDA: Limit use of 80mg Simvastatin	Lack of foundation for date description
941				ABB_SIM00270119 - ABB_SIM00270199	05/27/2009	Periodic Report	
942				ABB_S3_01568653 - ABB_S3_01568709	05/17/2010	Periodic Report	
943				ABB_S3_00089818 - ABB_S3_00089880	08/16/2010	Periodic Report	
944						METHOCEL™ Premium Cellulos Ethers (Low Viscosity) http://www.colorcon.com/products/core-excipients/immediate-release/methocel-low-viscosity	802
945				TV0023453 - TV0023458		Teva Pharmaceuticals USA, 500/20mg ANDA Section 3.2.P, Drug Product	
946				TV0004694 - TV0004698		Teva Pharmaceuticals USA, 750/20mg ANDA Section 3.2.P, Drug Product	
947				TV0000570 - TV0000575		Teva Pharmaceuticals USA, 1000/20mg ANDA Section 3.2.P, Drug Product	
948				TV0145624 - TV0145629		Teva Pharmaceuticals USA, 1000/40mg ANDA Section 3.2.P, Drug Product	
949				WT0000568 - WT0000569		Watson Laboratories, Inc. - Florida, ANDA Section 3.2.P.1.2, Draft Labeling Text	
950					10/19/2011	Curriculum Vitae, Stephen W. Schondelmeyer	
951					11/01/2000	Ernst, et al., *Prescription Medication Costs, A Study of Physician Familiarity,* 9 Arch. Fam. Med., pp. 1002-1007 (2000)	Lack of foundation for date description
952					09/12/2011	Schwartz, et al., *Communicating Uncertainties About Prescription Drugs to the Public,* 171(16) Arch. Intern. Med., pp. 1463-1468 (2011)	
953					04/03/2008	Kastelein, et al., *Simvastatin with or without Ezetimibe in Familial Hypercholesterolemia,* 358(14) N. Engl. J. Med., pp. 1431-1443 (2008)	
954						Baycol Recall Information	402, 802
955						Baycol Lawsuits	402, 802
956						Definition: Hyperlipidemia	802
957						Definition: Dyslipidemia	802

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
958						Centers for Disease control and Prevention, Facts About Cholesterol	
959						High Blood Choleseterol, What you need to know	
960					01/01/2010	Table 95, Selected prescription drug classes used in the past month, by sex and age: United States, selected years 1988-1994 through 2005-2008 (Health United States 2010)	106, Lack of foundation for date description
961				ABB_S3_00597858 - ABB_S3_00598047	01/01/2010	Abbott Laboratories, Inc., Pharmaceutical Products Division, 2010 Update PPG Review	Lack of foundation for date description
962				ABB_SIM00696200 - ABB_SIM00696203	1/1/2005 - 12/1/2010	IMS Data	Lack of foundation for date description
963			SIM-312 (Smith)	ABB_SIM00949898 - ABB_SIM00949904	6/1/2005 - 5/1/2011	IMS Data	Lack of foundation for date description
964						Kos Pharmaceuticals, Inc. - Company History	802
965					11/01/2009	Drug Class Review, HMG-CoA Reductase Inhibitors (statins) and Fixed-dose Combination Products Containing a Statin, Final Report, Update 5 (Oregon Health & Science University)	Lack of foundation for date description
966				ABB_SIM00577568 - ABB_SIM00577573	01/01/2008	Pharmaceutical Products Division, 2008 Plan - Key Product P&L, Dyslipidemia Franchise	Lack of foundation for date description
967				ABB_S3_01490358	12/21/2007	Talking Points re: Advicor	
968				ABB_S2_02812954 - ABB_S2_02812955	01/01/2009	2009 Update, Pharmaceutical Products Division, Simcor Summary	Lack of foundation for date description
969				ABB_S3_01906468 - ABB_S3_01906475	08/07/2009	Email correspondence regarding SIMCOR Gaiting and attempt to "Break Even"	
970			SIM-321 (Smith)	ABB_S3_00318525 - ABB_S3_00318537	06/01/2009	ROI Assessment, Simcor Sattellite Program (Sep-08)	Lack of foundation for date description
971				ABB_S3_00706213 - ABB_S3_00706223	12/01/2009	2010 Brand Plan, Simcor, niacin Extended-Release/simvastatin Tablets	Lack of foundation for date description
972				ABB_S2_02813095 - ABB_S2_02813103	04/13/2009	Email correspondence regarding Update questions	
973			SIM-303 (Smith)	ABB_S3_01813704 - ABB_S3_01813708	08/26/1997	FDA Letter to Kos Pharmaceuticals, Inc.	802, 403
974			SIM-323 (Smith)	ABB_S2_00662817 - ABB_S2_00662824	01/01/2004	Low HDL-C is Like an Accident Waiting to Happen	Lack of foundation for date description
975			SIM-326 (Smith)	ABB_S2_00246872 - ABB_S2_00246890	07/01/2007	Niaspan, Annotated Sales Aid	Lack of foundation for date description
976			SIM-325 (Smith)	ABB_S2_00566646 - ABB_S2_00566650	11/01/2005	Think Higher…Think Niaspan®	Lack of foundation for date description
977				ABB_S3_01209208 - ABB_S3_01209211	04/27/2007	Email correspondence regarding Follow Up Items from Tuesday meeting with Sudler	
978				ABB_S2_00070906 - ABB_S2_00070910		HDL-Challenge, Raise Good Choleseterol in CHD Patients	
979				ABB_S2_00185255	07/07/2000	Memorandum regarding Heart Alliance - Managed Care (HAMCO)	

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980				ABB_S2_00242238 - ABB_S2_00242266	04/01/2007	NEW Niaspan Tablet Formulation Tactical Thrusts to Support Launch	Lack of foundation for date description
981			SIM-320 (Smith)	ABB_S2_00144587 - ABB_S2_00144590	04/26/2000	Memorandum regarding Heart Alliance Incentive Program	
981				ABB_S3_00588378 - ABB_S3_00588387	06/08/2009	2009 Niaspan Key Contributors to Drive Share Momentum	
983				ABB_S2_00242714 - ABB_S2_00242750	12/01/2007	Niaspan/SIMCOR Flushing and Cordaptive Preparedness Strategy	Lack of foundation for date description
984				ABB_S2_00247374 - ABB_S2_00247388	12/05/2007	PPD Launch of Niaspan	403 (cumulative)
985				ABB_SIM00568778 - ABB_SIM00568876	04/22/2008	2008 Situation Analysis, Niaspan and SIMCOR	
986				ABB_S2_00246476 - ABB_S2_00246494		Strategic Plan, 2007-2009, Product	
987				ABB_S3_00084328 - ABB_S3_00084329		SIMCOR 2010 Update Pharmaceutical Products Division Franchise Summary	
988				ABB_S3_00059856 - ABB_S3_00059859		Fall 2010 Regional Meetings, SIMCOR/NIASPAN Video Outline, Version 2	
989			SIM-328 (Smith); SIM-229 (Bottorff)		11/01/2010	Pharmacy Benefits Management - Medical Advisory Panel-VISN Pharmacist Executives Ez-Minutes	802, Lack of foundation for date description
990					09/01/2008	SLO-NIACIN®: Lower Your Cholesterol	802, Lack of foundation for date description
991			SIM-305 (Smith)	ABB_S3_01348927 - ABB_S3_01348932	01/11/2002	FDA Letter to Kos Pharmaceuticals, Inc.	802
992				ABB_S2_00072742 - ABB_S2_00072745	07/02/1997	FDA Letter to Kos Pharmaceuticals, Inc.	802
993				ABB_S3_01349517 - ABB_S3_01349527	07/22/2010	Physician Interactive Overview	403 (cumulative)
994					10/04/2011	Abbott v. Teva: Stipulation	402
995				ABB_SIM00695532 - ABB_SIM00695625	12/31/2001	Kos Pharmaceuticals, Inc. Form 10-K	Lack of foundation for date description
996				ABB_S3_01297337 - ABB_S3_01297367	01/01/2009	2010 Brand Plan, Simcor, niacin Extended-Release/simvastatin Tablets	Lack of foundation for date description
997				ABB_S2_00180465 - ABB_S2_00180466	10/23/2001	Memorandum regarding 2002 Budget Rationale	
998				ABB_S2_00071708 - ABB_S2_00071716		Kos Pharmaceuticals, Inc. 2001 Operating and Financial Review	
999			SIM-322 (Smith)	ABB_S2_00070889 - ABB_S2_00070890		35 niacin brands all lack one key ingredient: FDA Scrutiny	
1000				ABB_S3_00467622 - ABB_S3_00467623	07/25/2008	Email correspondence regarding Florida - Veterans Admin VISN 8 switching Niaspan to Niacin	
1001				ABB_S2_02385790 - ABB_S2_02385797		Why your doctor has prescribed Niaspan® (niacin extended-release tablets)	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1002				ABB_S3_00599609 - ABB_S3_00599641	06/01/2010	Dyslipidemia Marketing Mix Data Review (Simcor)	Lack of foundation for date description
1003				ABB_S3_01215820 - ABB_S3_01215822	03/30/2010	Email correspondence regarding Heart Alliance and CSM Flushing Education	
1004				ABB_S2_00251655 - ABB_S2_00251744	06/04/2008	Dyslipidemia Long-term Strategy Review	
1005			SIM-324 (Smith)	ABB_S2_00876044 - ABB_S2_00876065		Get regressive with NIASPAN®	
1006				ABB_S3_01269026 - ABB_S3_01269027		Simcor Best Practices	403 (cumulative)
1007				ABB_S3_00637897	08/21/2008	Email correspondence regarding Niaspan or N on the side of the Bulldozer - Roizen Request and Med/Reg Feedback	
1008				ABB_S2_00253515 - ABB_S2_00253536		2008 Plan, Pharmaceutical Products Division, Niaspan Summary	
1009				ABB_S3_00073340 - ABB_S3_00073388	10/01/2006	Niaspan CF Opportunity Exploration, Prepared for Kos Pharmaceuticals by PharmaSight Research LLC	Lack of foundation for date description
1010				ABB_S2_00149168 - ABB_S2_00149188	02/07/1997	License Agreement between Upsher-Smith Laboratories and Kos Pharmaceuticals, Inc. with exhibits	403 (cumulative)
1011				ABB_S2_00149335 - ABB_S2_00149372	01/09/2002	Patent Purchase and Assignment Agreement between Upsher-Smith Laboratories, Inc. and Kos Pharmaceuticals, Inc.	403 (cumulative)
1012				ABB_SIM00520457 - ABB_SIM00520458	03/04/2002	Kos Pharmaceuticals Files Patent Infringement Lawsuit Against Barr Laboratories	402, 802
1013				ABB_SIM00552721 - ABB_SIM00552751	02/28/2003	Kos v. Barr: Reply to Counterclaims and Counterclaims for Declaratory Judgment	402
1014			SIM-313 (Smith)	ABB_S2_00157311	02/24/1998	Letter from B. Jordan, Synthélabo to Mukesh Patel, Kos Pharmaceuticals, Inc.	402, 802
1015			SIM-314 (Smith)	ABB_S2_00176174 - ABB_S2_00176175	08/29/2001	Letter from Mark Lee, Wyeth-Ayerst Pharmaceuticals to Christopher Kiritsy, Kos Pharmaceuticals, Inc.	402, 802
1016			SIM-316 (Smith)	ABB_S2_00310465		Merck KGaA Niaspan Deal Summary	
1017				ABB_S2_00948605 - ABB_S2_00948613		2009 Niaspan Strategic Plan	
1018				ABB_S3_01740877 - ABB_S3_01740878	04/14/2008	Email correspondence regarding Simcor Objections	
1019				ABB_SIM01259606		Video file	403 (cumulative)
1020				ABB_SIM00949892 - ABB_SIM00949897		Niaspan Sales Projections	
1021				ABB_SIM00024891 - ABB_SIM00025286	04/24/1996	Protocol 89/04 Final Report (Revision #1): A Single-Blind Placebo-Controlled Pilot Study Comparing the Effect of Once-a-Day Versus Twice-a-Day Dosing of Niaspan™ on Serum Lipids	
1022				ABB_S2_00154772 - ABB_S2_00154774	08/01/1989	Mullin, et al., *Fulminant Hepatic Failure after Ingestion of Sustained-Release Nicotinic Acid,* 111 Ann. Intern. Med., pp. 253-255 (1989)	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1023				ABB_SIM00566550 - ABB_SIM00566552	07/11/1990	Henkin, et al., *Rechallenge With Crystalline Niacin After Drug-Induced Hepatitis From Sustained-Release Niacin,* 264(2) JAMA, pp. 241-243 (1990)	
1024				ABB_SIM00883470 - ABB_SIM00883475	01/01/1991	Etchason, et al., *Niacin-Induced Hepatitis: A Potential Side Effect With Low-Dose Time-Release Niacin,* 66 Mayo Clin. Proc., pp. 23-28 (1991)	Lack of foundation for date description
1025			SIM-228 (Bottorff)	ABB_S2_00154784 - ABB_S2_00154788	06/27/1991	Rader, et al., *Hepatic Toxicity of Unmodified and Time-Release Preparations of Niacin,* 92 Am. J. Med., pp. 77-81 (1992)	
1026					07/11/1990	Hodis, *Acute Hepatic Failure Associated with the Use of Low-Dose Sustained-Release Niacin,* 264(2) JAMA, p. 181 (1990)	
1027					11/01/1989	Knopp, *Niacin and Hepatic Failure,* 111(9) Ann. Intern. Med., p. 769 (1989)	Lack of foundation for date description
1028			SIM-223 (Bottorff)	ABB_SIM00566553 - ABB_SIM00566560	05/21/1991	Henkin, et al., *Niacin Revisited: Clinical Observations on an Important but Underutilized Drug,* 91 Am. J. Med., pp. 239-246 (1991)	
1029				ABB_SIM00025143		NIASPAN Protocol 89/04 Excerpt, Appendix D.9, Lipids	106, 403 (cumulative)
1030				ABB_S2_00014977 - ABB_S2_00014993		NIASPAN Protocol 91/15 Excerpt, Laboratory Values, Lipids	106, 403 (cumulative)
1031				ABB_S2_00011346		NIASPAN Protocol 91/05 Excerpt, Patient Baseline Lipid Values	106, 403 (cumulative)
1032				ABB_S2_00013877		NIASPAN Protocol 91/15 Excerpt, Patient Baseline Lipid Values	106, 403 (cumulative)
1033				ABB_SIM00019325		NIASPAN Protocol 91/09 Excerpt, Patient Baseline Lipid Values	106, 403 (cumulative)
1034				ABB_S2_00221540		NIASPAN Protocol 96/05 Excerpt, Triglycerides	106, 403 (cumulative)
1035				ABB_S2_00008764 - ABB_S2_00008766	01/13/1992	Protocol Number 91/04, Section 9: Exclusion Criteria	106, 403 (cumulative)
1036				ABB_S2_00012118 - ABB_S2_00012119	01/13/1992	Protocol Number 91/05, Section 9: Exclusion Criteria	106, 403 (cumulative)
1037				ABB_S2_00014322 - ABB_S2_00014323	11/08/1993	Protocol Number 91/15 Amendment #2, Section 9: Exclusion Criteria	106, 403 (cumulative)
1038				ABB_SIM00025745 - ABB_SIM00025746	03/28/1994	Protocol Number 94/01, Section 9: Exclusion Criteria	106
1039				ABB_SIM00566568 - ABB_SIM00566573	08/24/2001	Kane, et al., *Cholesterol and Clycemic Effects of Niaspan in Patients with Type 2 Diabetes,* 21(12) Pharmacotherapy, pp. 1473-1478 (2001)	
1040				ABB_SIM00566527 - ABB_SIM00566535	07/22/2002	Grundy, et al., *Efficacy, Safety, and Tolerability of Once-Daily Niacin for the Treatment of Dyslipidemia Associated With Type 2 Diabetes,* 162 Arch. Intern. Med., pp. 1568-1576 (2002)	
1041				ABB_S3_01348900 - ABB_S3_01348902	05/12/2003	FDA Letter to Kos Pharmaceuticals, Inc. regarding Advent rejection	802
1042				ABB_S3_00714547 - ABB_S3_00714652	03/12/2007	Final Clinical Study Report: 019-01-03-CR	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1043				ABB_S3_00007663 - ABB_S3_00007673		M10-013 Clinical Study Report - SUPREME	106
1044			SIM-372 (Sacks)	ABB_S2_00106170 - ABB_S2_00106173	08/08/1990	Garg & Grundy, *Nicotinic Acid as Therapy for Dyslipidemia in Non-Insulin-Dependent Diabetes Mellitus,* 264 JAMA, pp. 723-726 (1990)	403 (cumulative)
1045			SIM-364 (Sacks)	ABB_SIM00566188 - ABB_SIM00566450		Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III "ATP III"), Final Report	
1046					12/21/1964	Parsons, *The Effect of Nicotinic Acid on the Liver,* Niacin in Vascular Disorders and Hyperlipidemia (1964)	
1047					11/01/1996	Aronov, et al., *Clinical Trial of Wax-Matrix Sustained-Release Niacin in a Russian Population With Hypercholesterolemia,* 5 Arch. Fam. Med., pp. 567-575 (1996)	Lack of foundation for date description
1048				ABB_SIM01198925 - ABB_SIM01198998	12/31/1998	Kos Pharmaceuticals, Inc. 10-K Report	Lack of foundation for date description
1049			SIM-367 (Sacks)	ABB_SIM00566005 - ABB_SIM00566187	09/01/1993	Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II "ATP II"), Final Report	Lack of foundation for date description
1050						World Health Organization "WHO" Geneva Consultation: Definition, Diagnosis and Classification of Diabetes Mellitus and its Complications	
1051				ABB_S2_00221449 - ABB_S2_00221450		Protocol 96/05 Final Report, Section 3.3.2 Exclusion Criteria	
1052					1/1/1961 - 6/1/1961	Parsons, *Studies of Nicotinic Acide Use in Hypercholesteremia,* Archives of Internal Medicine (1961)	Lack of foundation for date description
1053				ABB_SIM00566582 - ABB_SIM00566589	09/01/1998	Knopp, et al., *Equivalent Efficacy of a Time-Release Form of Niacin (Niaspan) Given Once-a-Night Versus Plain Niacin in the Management of Hyperlipidemia,* 47(9) Metabolism, pp. 1097-1104 (1998)	Lack of foundation for date description
1054				ABB_SIM00566456 - ABB_SIM00566460	07/01/2001	Birjmohun, et al., *Increasing HDL cholesterol with extended-release nicotinic acid: from promise to practice,* 62 Netherlands J. Med., pp. 229-233 (2004)	Lack of foundation for date description
1055					11/08/2011	Abbott v. Teva: Deposition Transcript of Daniel C. Smith, Ph.D.	802
1056			SIM-301 (Smith)		06/01/2011	Simcor® Package Insert	403 (cumulative), Lack of foundation for date description
1057			SIM-302 (Smith)	ABB_SIM01259709 - ABB_SIM01259746	02/01/2011	Supplement Approval letter from the FDA regarding Advicor Tablets	
1058			SIM-304 (Smith)	ABB_S3_01347285 - ABB_S3_01347291	07/13/2001	Letter from Thomas Abrams, Director, Food and Drug Administration, to Adrain Adams, President, Kos Pharmaceuticals, Inc. (July 13, 2001)	802, 403 (cumulative)
1059			SIM-307 (Smith)	ABB_SIM00572395 - ABB_SIM00572527	05/01/2004	Advicor®/Niaspan® Phase II: Awareness, Attitude, and Usage Study	Lack of foundation for date description
1060			SIM-308 (Smith)	ABB_S2_00269771 - ABB_S2_00269988	05/28/2008	Dyslipidemia Q1 2008 Attitudes, Awareness, and Usage Report: Niaspan and Simcor, *March Major AAU with April Awareness Tracker Results*	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1061			SIM-309 (Smith)	ABB_SIM01153515 - ABB_SIM01153574	06/11/2010	Dyslipidemia Market AAU 1st Quarter 2010 (M10)	
1062			SIM-310 (Smith)	ABB_S2_02639279 - ABB_S2_02639293	12/05/2007	PPD Launch of Niaspan	403 (cumulative)
1063			SIM-315 (Smith)	ABB_S2_00213119 - ABB_S2_00213188	10/23/2002	Distribution, Patent & Trademark License, Marketing and Supply Agreement between Kos Pharmaceuticals, Inc. and Merck KGaA	403 (cumulative)
1064			SIM-317 (Smith)	ABB_S2_01113821 - ABB_S2_01113865	04/12/2005	License and Manufacturing Agreement between Barr Laboratories, Inc., and Kos Life Sciences, Inc.	403 (cumulative)
1065			SIM-318 (Smith)	ABB_S2_01113798 - ABB_S2_01113820	04/12/2005	Settlement and License Agreement between Kos Pharmaceuticals, Inc. and Barr Laboratories, Inc.	403 (cumulative)
1066			SIM-319 (Smith)	ABB_SIM00523007 - ABB_SIM00523044	01/09/2002	Patent Purchase and Assignment Agreement between Upsher-Smith Laboratories, Inc. and Kos Pharmaceuticals, Inc.	403 (cumulative)
1067			SIM-327 (Smith)	ABB_S2_00660641 - ABB_S2_00660648		Think Higher, HDL-C, Think Niaspan (niacin extended-release tablets)	
1068					11/15/2011	Abbott v. Teva: Deposition Transcript of Michael B. Bottorff, Pharm. D.	802
1069					11/16/2011	Abbott v. Teva: Deposition Transcript of Michael B. Bottorff, Pharm. D.	802
1070			SIM-202 (Bottorff)			Curriculum Vitae: Michael B. Bottorff, Pharm.D., FCCP, CLS	
1071			SIM-207 (Bottorff)	ABB_SIM01154524 - ABB_SIM01154529	12/21/2000	Piepho, *The Pharmacokinetics and Pharmacodynamics of Agents Proven to Raise High-Density Lipoprotein Cholesterol,* 86(suppl.) Am. J. Cardiol., pp. 35L-40L (2000)	
1072			SIM-208 (Bottorff)	ABB_SIM01263130 - ABB_SIM01263149	08/11/2010	Mullangi, et al., *Niacin and its metabolites: role of LC-MS/MS bioanalytical methods and update on clinical pharmcology. An overview,* 25 Biomed. Chromatogr., pp. 218-237 (2011)	
1073			SIM-212 (Bottorff)		06/17/2010	Reiche, et al., *Pharmacokinetics and dose recommendations of Niaspan in chronic kidney disease and dialysis patients,* 26 Nephrol. Dial. Transplant, pp. 276-282 (2011)	
1074			SIM-214 (Bottorff)	ABB_SIM00573340 - ABB_SIM00573365	03/01/2003	Guidance for Industry, Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations (CDER Revision 1)	Lack of foundation for date description
1075			SIM-219 (Bottorff)	ABB_SIM00255097 - ABB_SIM00255529	11/30/1995	Protocol Number 91/19, Final Report Addendum: A Multiple-Dose, Cross-Over Study of the Steady-State Pharmacokinetics and Urinary Excretion of Niacin and its Major Metabolites from Niaspan in Reference to an Immediate-Release Formulation	
1076			SIM-221 (Bottorff)			Handwritten Notes	802, 106, 901, 402
1077			SIM-222 (Bottorff)	ABB_SIM00566590 - ABB_SIM00566595	12/21/2000	Knopp, *Evaluating Niacin in its Various Forms,* 86(suppl) Am. J. Cardiol., pp. 51L-56L (2000)	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1078			SIM-224 (Bottorff)	ABB_SIM00539229 - ABB_SIM00539237	07/01/1985	Knopp, et al., *Contrasting Effects of Unmodified and Time-Release Forms of Niacin on Lipoproteins in Hyperlipidemic Subjects: Clues to Mechanism of Action of Niacin* , 34(7) Metabolism, pp. 642-650 (1985)	Lack of foundation for date description
1079			SIM-230 (Bottorff)			Worz, et al., *Treating Dyslipidemic Patients with Lipid-Modifying and Combination Therapies,* 23(5) Pharmacother., pp. 625-637 (2003)	
1080					11/15/2011	Abbott v. Teva: Deposition Transcript of Robert O. Williams, Ph.D.	802
1081					11/16/2011	Abbott v. Teva: Deposition Transcript of Robert O. Williams, Ph.D.	802
1082			SIM-330 (Williams)			Curriculum Vitae, Robert O. (Bill) Williams III	
1083			SIM-331 (Williams)		06/30/2003	Mahaguna, et al., *Influence of hydroxypropyl methylcellulose polymer on in vitro and in vivo performance of controlled release tablets containing alprazolam,* 56 Eur. J. Pharm. Biopharm., pp. 461-468 (2003)	
1084			SIM-332 (Williams)			Williams, et al., *Investigation of Excipient Type and Level on Drug Release from Controlled Release Tablets Containing HPMC,* 7(2) Pharm. Dev. Tech., pp. 181-193 (2002)	
1085			SIM-336 (Williams)	ABB_S2_01939657 - ABB_S2_01939759		Kos Pharmaceuticals, Inc. NDA 20-381, Human Pharmacokinetics and Bioavailability	
1086			SIM-357 (Williams)		01/01/1990	USP XXII, The United States Pharmacopeia (Twenty-Second Revision)	Lack of foundation for date description
1087			SIM-359 (Williams)		04/08/2010	Abbott v. Lupin: Supplemental Declaration of Thomas S. Foster, Pharm.D. in Support of Plaintiffs' Responsive Claim Construction Brief	802
1088				ABB_S2_00031178 - ABB_S2_00031206	05/24/1996	The Comparative Bioavailability of Two Sustained-Release Niacin Products Relative to Niaspan®	
1089				ABB_S2_00031174	07/10/1996	Letter from David Bova, Vice President, Research and Development, to Solomon Sobel, Director, Division of Metabolism and Endocrine Drug Products (July 10, 1996)	
1090				ABB_S2_00032022- ABB_S2_00032332	05/28/1997	Department of Health and Human Services: Public Health Services, Food and Drug Administration. Investigational New Drug Application (IND) Report re: IND No. 34,613	
1091					01/01/2004	Kos Pharmaceuticals, Inc., International Directory of Company Histories, Vol. 63, pp. 232-235 (2004)	403 (cumulative), 802, Lack of foundation for date description
1092			SIM-329 (Smith)	ABB_S2_00224771	11/13/2001	Internal Memorandum regarding Record of conversation with Andy Bodnar, MD of Bristol-Myers Squibb	802
1093				ABB_SIM00521514 - ABB_SIM00521544	02/28/2003	Kos v. Barr: Reply to Counterclaims and Counterclaims for Declaratory Judgment	403 (cumulative), 402
1094				ABB_S2_00197930 - ABB_S2_00198273	01/09/1997	Letter from Albert Infranco, DesignWrite Incorporated, to David Bova, Kos Pharmaceuticals with attachments	403 (cumulative)

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1095				ABB_S2_00153150	02/22/1999	Letter from Deyamira Taborda, Kos Pharmaceuticals, Inc., to Robert Knopp, Northwest Lipid Research Clinic	402
1096				ABB_S2_00176945	08/02/1996	Letter from Roger Pelletier, Kos Pharmaceuticals, Inc., to Robert Knopp, Northwest Lipid Research Clinic	402
1097				ABB_S2_00176957	09/15/1993	Letter from Sue Balandis, Kos Pharmaceuticals, Inc., to Robert Knopp, Northwest Lipid Research Clinic	
1098				ABB_S2_00176977 - ABB_S2_00176978	05/18/1993	Letter from David Bova, Kos Pharmaceuticals, Inc., to Robert Knopp, Northwest Lipid Research Clinic	
1099				ABB_S3_01605875 - ABB_S3_01605881	06/14/2007	Birjmohun, et al., *Safety and tolerability of prolonged-release niacotinic acid in statin-treated patients* , 23(7) Curr. Med. Res. Opin., pp. 1707-1713 (2007)	
1100				ABB_S2_00125592 - ABB_S2_00125593	06/13/1994	Letter from David Bova, Kos Pharmaceuticals, Inc., to Lars Carlson, King Gustav V Research Institute	
1101				ABB_S2_00125583	09/06/1994	Letter from David Bova, Kos Pharmaceuticals, Inc., to Lars Carlson, King Gustav V Research Institute	
1102				ABB_S2_00125584	06/21/1994	Letter from David Bova, Kos Pharmaceuticals, Inc., to Lars Carlson, King Gustav V Research Institute	402
1103				ABB_S2_02363237 - ABB_S2_02363240	04/09/2008	Email correspondence regarding Potential Investigator: James McKenney	
1104				ABB_S2_00261017 - ABB_S2_00261022		Manuscript Status, Clinical Applied Sciences	
1105				ABB_S2_00769606 - ABB_S2_00769607	10/17/2007	Correspondence regarding New Publications and News Articles in OLMS	
1106				ABB_S3_00904987 - ABB_S3_00905002		2008 SIMCOR Bibliography, Abbott Publications	
1107				ABB_S3_00444088 - ABB_S3_00444159	04/17/2008	The American Journal of Cariology VOL. 101 Niacin Therapy: An Evolving Paradigm for the Management of Mixed Dyslipidemia and Low High-Density Lipoprotein Choloesterol	
1108				ABB_S3_01331114 - ABB_S3_01331147	06/30/1905	Fruchart, et al., *The Residual Risk Reduction Initiative: A Call to Action to Reduce Residual Vascular Risk in Patients with Dyslipidemia,* 102[suppl.] Am. J. Cardiol., pp. 1K-34K (2008)	
1109				ABB_S2_00152429 - ABB_S2_00152432	05/01/2000	Email correspondence regarding AHA 2000 abstract	802
1110			SIM-369 (Sacks)		1/1/1989	U.S. Pharmacopeia drug information for the health professional. Rockville, Maryland: United States Pharmacopeia Convention, 1989: 1739-40	106, 403, 802, Lack of foundation for date description
1111				ABB_S2_00149213	7/24/1997	Letter from Dan Bell of KOS to Ian Troup at Upsher-Smith Laboratories	408
1112				ABB_S2_00149270- ABB_S2_00149307	1/9/2002	Patent Purchase and Assignment Agreement between Upsher-Smith Laboratories, Inc. and Kos Pharmaceuticals, Inc.	403 (cumulative)
1113				ABB_S2_00149308 - ABB_S2_00149319	1/9/2002	Security Agreement between Kos Pharmaceuticals and Upsher-Smith Laboratories	
1114				ABB_S2_00149320 - ABB_S2_00149322	1/9/2002	Assignment between Upsher-Smith Laboratories and Kos Pharmaceuticals, Inc.	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1115				ABB_S2_00149323 - ABB_S2_00149324	1/9/2002	Letter from Upsher-Smith to Kos Pharmaceuticals regarding amendment to agreement	
1116				ABB_S2_00149327 - ABB_S2_00149329	1/9/2002	United States Patent Assignment by Upsher-Smith Laboratories and Kos Pharmaceuticals regarding '145 and '181 patents	
1117				ABB_S2_00245848 - ABB_S2_00245856	00/00/2008	Presentation, dyslipidemia franchise product profiles and competitive product profiles	
1118				ABB_S2_00251293 - ABB_S2_00251310	10/28/2008	Presentation, Marianne Sutcliffe, General Manager, Niaspan, SIMCOR and Advicor	
1119				ABB_S2_00347166 - ABB_S2_00347168		Commercial Synergies for Niaspan and SIMCOR with sales forecasts for 2006-2008	
1120				ABB_S2_00577043 - ABB_S2_00577060	06/00/2007	Marketing brochure, Niaspan - Raise. Regress. Reduce.	
1121				ABB_S2_00988140 - ABB_S2_00988167	03/00/2009	Marketing brochure, Get Regressive with Niaspan.	
1122						Withdrawn, refer to DTX-540	802
1123				ABB_SIM_00573323	05/00/2010	Niaspan advertisement, Sis, you wrote your doctor	
1124				ABB_SIM_00573335	05/00/2010	Niaspan advertisement, Hey, big brother	
1125				ABB_SIM_00575938	3/24/2010	Movie file, Niaspan advertisement, Bonnie's Sister	403 (cumulative)
1126				ABB_SIM_00575939	3/24/2010	Movie file, Niaspan advertisement, Pete's Brother	
1127				ABB_SIM_00577606 - ABB_SIM_00577623		Simcor marketing materials, One treatment, Two Targets, powerful dual-lipid management	
1128				ABB_SIM_00577642 - ABB_SIM_00577655		Simcor marketing materials, In Simvastatin Patients, Drive HDL-C Higher	
1129				ABB_SIM_00577656 - ABB_SIM_00577676		Simcor marketing materials, Aggressive targets demand comprehensive lipid management	
1130				ABB_SIM_00577705 - ABB_SIM_00577720		Simcor marketing materials, One treatment, Two Targets, Powerful dual-lipid management, Aim for both	
1131				ABB_SIM_00577721 - ABB_SIM_00577746		Simcor marketing materials, SIMCOR - aggressive targets demand comprehensive lipid management - all at once	
1132				ABB_SIM_00579092 - ABB_SIM_00579112		Simcor marketing materials, in Simvastatin Patients, Drive HDL-C Higher, new 40 mg strengths	
1133				ABB_SIM_00886716 - ABB_SIM_00886747	12/7/2010	USA v. Kos Pharmaceuticals, Middle District of Louisiana, Deferred Prosecution Agreement	402, 403, 802 (subject to the parties' 9/29/11 stipulation)
1134				ABB_SIM_00886802 - ABB_SIM_00886813	00/00/2009	2010 Niaspan Brand Plan	403 (cumulative)
1135				ABB_SIM_00946002 - ABB_SIM_00946690		IMS data	
1136				ABB_SIM_01152091 - ABB_SIM_01152097		Presentation, Project P: Niaspan Franchise	
1137				ABB_SIM_01159779 - ABB_SIM_01159782		IMS data	403 (cumulative)

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1138					5/4/2010	"Complaint," *Abbott Laboratories and Abbott Respiratory LLC, v. Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. – Florida and Watson Pharma, Inc.,* United States District Court for the District of Delaware	
1139					3/25/2011	"Complaint," *Abbott Laboratories and Abbott Respiratory LLC, v. Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. – Florida and Watson Pharma, Inc.,* United States District Court for the District of Delaware	
1140					9/12/2011	Letter to Kevin S. Prussia (William Cutler Pickering Hale and Dorr LLP) from Thomas R. Johnson (Carlson, Caspers, Vanderburgh & Lindquist).	402, 802
1141					4/1/2011	"Plaintiff's Second Supplemental Response to Defendants' Joint Interrogatory No. 6"	
1142					12/31/2006	Abbott Laboratories, Form 10-K for the fiscal year ended December 31, 2006.	Lack of foundation for date description
1143					4/16/2008	"Abbott Laboratories 1st Quarter Results," Regulatory News Service, April 16, 2008.	
1144					10/3/2002	"Answering Brief of Upsher-Smith Laboratories, Inc.," *In the Matter of Schering-Plough Corporation,Upsher-Smith Laboratories, Inc. and American Homes Products Corporation,* United States Federal Trade Commission, Docket No. 9297, October 3, 2002 [Public Record Version].	402, 802
1145					7/2/1905	Aventis Pharma S.A. v. Hospira, Inc., 743 F. Supp. 2d 305, 348 (D. Dela. 2010).	402, 802
1146					10/12/2011	"Changing from Niaspan to Slo-Niacin Tablets, Information for Patients" available at www.permanente.net/kaiser/pdf/62664.pdf accessed October 12, 2011.	901, 403, 802
1147					10/2006	Congressional Budget Office, "A CBO Study: Research and Development in the Pharmaceutical Industry," October 2006.	
1148					06/2003	Ernst R. Berndt et al., "Consumption Externalities and Diffusion in Pharmaceutical Markets: Antiulcer Drugs," The Journal of Industrial Economics, Vol. LI, No. 2, June 2003.	
1149					03/1999	Ernst R. Berndt et al., "Network Effects and Diffusion in Pharmaceutical Markets: Antiulcer Drugs," NBER Working Paper No. 7024, March 1999.	
1150					01/2011	"Guidance for Industry, Process Validation: General Principles and Practices," January 2011 available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070336.pdf accessed October 6, 2011.	
1151					09/22/2011	http://www.fda.gov/AboutFDA/WhatWeDo/WhatFDARegulates/default.htm accessed September 22, 2011.	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1152					09/22/2011	http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm accessed September 22, 2011.	
1153					09/30/2011	http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm accessed September 30, 2011.	
1154					09/30/2011	http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/default.htm accessed September 30, 2011.	
1155					09/22/2011	http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/default.htm accessed September 22, 2011.	
1156					09/22/2011	http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm accessed September 22, 2011.	
1157					09/30/2011	http://www.fda.gov/Food/DietarySupplements/ConsumerInformation/ucm110417.htm accessed September 30, 2011.	
1158					7/3/1905	In re Huai-Hung Kao, 639 F.3d 1057, 1069-70 (Fed. Cir. 2011).	402, 802
1159					06/27/2002	"Initial Decision," *In the Matter of Schering-Plough Corporation, Upsher-Smith Laboratories, and* American Home Products Corporation, United States Federal Trade Commission, Docket No. 9297, June 27, 2002 [Public Record Version].	402, 802
1160					02/21/2002	"Kos Announces Record Fourth Quarter and Year-End Results," *PR Newswire* , February 21, 2002.	
1161					11/12/1997	"Kos Pharmaceuticals Announces Quarterly Results," *PR Newswire* , November 12, 1997.	
1162					12/31/1998	Kos Pharmaceuticals, Inc., Form 10-K for the fiscal years ended December 31, 1998.	Lack of foundation for date description
1163					12/31/2001	Kos Pharmaceuticals, Inc., Form 10-K for the fiscal years ended December 31, 2001.	Lack of foundation for date description
1164					12/31/2004	Kos Pharmaceuticals, Inc., Form 10-K for the fiscal years ended December 31, 2004.	Lack of foundation for date description
1165					2005	Schering-Plough Corporation v. Federal Trade Commission, 402 F.3d 1056 (11th Cir. 2005).	402, 802
1166					10/10/2011	"Truthful Prescription Drug Advertising and Promotion: The Prescriber's Role" available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/PrescriptionDrugAdvertisingandPromotionalLabeling/UCM209847.pdf accessed October 10, 2011.	
1167					07/2008	United States Government Accountability Office, "Prescription Drugs, FDA's Oversight of the Promotion of Drugs for Off-Label Uses," July 2008.	
1168					09/23/2011	FDA Orange Book data for Simcor available at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm accessed September 23, 2011.	

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1169					09/23/2011	FDA Orange Book data for Niaspan available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/temptn.cfm accessed September 23, 2011.	
1170					09/23/2011	FDA Orange Book data for Advicor available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/temptn.cfm accessed September 23, 2011.	
1171					9/29/2011	FDA Orange Book data for Niacin available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/tempai.cfm accessed September 29, 2011.	
1172				TV0044195 - TV0044204	07/01/1985	Knopp, et al., *Contrasting Effects of Unmodified and Time-Release Forms of Niacin on Lipoproteins in Hyperlipidemic Subjects: Clues to Mechanism of Action of Niacin* , 34(7) Metabolism, pp. 642-650 (1985)	403 (cumulative), Lack of foundation for date description
1173				ABB_SIM00525983 - ABB_SIM00526159	10/27/2003	Kos v. Barr: Kos' Responses to Barr's Interrogatory Nos. 11-23	402
1174					12/7/2010	Kos Pharmaceuticals to Pay More Than $41 Million to Resolve Kickback and Off-Label Promotion Allegations	802, 403, 402
1175					9/24/2010	Missouri to get $226,000 in Kos drug suit settlement	802, 403, 402
1176				ABB_TEVA001038 - ABB_TEVA001052	12/7/2010	State Settlement Agreement and Release (Alaska)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1177				ABB_TEVA001053 - ABB_TEVA001067	12/7/2010	State Settlement Agreement and Release (Alabama)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1178				ABB_TEVA001068 - ABB_TEVA001082	12/7/2010	State Settlement Agreement and Release (Arkansas)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1179				ABB_TEVA001083 - ABB_TEVA001098	12/7/2010	State Settlement Agreement and Release (California)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1180				ABB_TEVA001099 - ABB_TEVA001113	12/7/2010	State Settlement Agreement and Release (Colorado)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1181				ABB_TEVA001114 - ABB_TEVA001128	12/7/2010	State Settlement Agreement and Release (Connecticut)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1182				ABB_TEVA001129 - ABB_TEVA001145	12/7/2010	State Settlement Agreement and Release (Delaware)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1183				ABB_TEVA001146 - ABB_TEVA001160	12/7/2010	State Settlement Agreement and Release (District of Columbia)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1184				ABB_TEVA001161 - ABB_TEVA001175	12/7/2010	State Settlement Agreement and Release (Florida)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1185				ABB_TEVA001176 - ABB_TEVA001190	12/7/2010	State Settlement Agreement and Release (Georgia)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1186				ABB_TEVA001191 - ABB_TEVA001205	12/7/2010	State Settlement Agreement and Release (Hawaii)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1187				ABB_TEVA001206 - ABB_TEVA001220	12/7/2010	State Settlement Agreement and Release (Idaho)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1188				ABB_TEVA001221 - ABB_TEVA001235	12/7/2010	State Settlement Agreement and Release (Illinois)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1189				ABB_TEVA001236 - ABB_TEVA001250	12/7/2010	State Settlement Agreement and Release (Indiana)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1190				ABB_TEVA001251 - ABB_TEVA001266	12/7/2010	State Settlement Agreement and Release (Iowa)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1191				ABB_TEVA001267 - ABB_TEVA001281	12/7/2010	State Settlement Agreement and Release (Kansas)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1192				ABB_TEVA001282 - ABB_TEVA002196	12/7/2010	State Settlement Agreement and Release (Kentucky)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1193				ABB_TEVA001297 - ABB_TEVA001311	12/7/2010	State Settlement Agreement and Release (Louisiana)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1194				ABB_TEVA001312 - ABB_TEVA001326	12/7/2010	State Settlement Agreement and Release (Maine)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1195				ABB_TEVA001327 - ABB_TEVA001341	12/7/2010	State Settlement Agreement and Release (Maryland)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1196				ABB_TEVA001342 - ABB_TEVA001356	12/7/2010	State Settlement Agreement and Release (Massachusetts)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1197				ABB_TEVA001357 - ABB_TEVA001371	12/7/2010	State Settlement Agreement and Release (Michigan)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1198				ABB_TEVA001372 - ABB_TEVA001386	12/7/2010	State Settlement Agreement and Release (Minnesota)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1199				ABB_TEVA001387 - ABB_TEVA001401	12/7/2010	State Settlement Agreement and Release (Mississippi)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1200				ABB_TEVA001402 - ABB_TEVA001416	12/7/2010	State Settlement Agreement and Release (Missouri)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1201				ABB_TEVA001417 - ABB_TEVA001431	12/7/2010	State Settlement Agreement and Release (Montana)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1202				ABB_TEVA001432 - ABB_TEVA001446	12/7/2010	State Settlement Agreement and Release (Nebraska)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1203				ABB_TEVA001447 - ABB_TEVA001461	12/7/2010	State Settlement Agreement and Release (Nevada)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1204				ABB_TEVA001462 - ABB_TEVA001476	12/7/2010	State Settlement Agreement and Release (New Hampshire)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1205				ABB_TEVA001477 - ABB_TEVA001491	12/7/2010	State Settlement Agreement and Release (New Jersey)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1206				ABB_TEVA001492 - ABB_TEVA001506	12/7/2010	State Settlement Agreement and Release (New Mexico)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1207				ABB_TEVA001507 - ABB_TEVA001521	12/7/2010	State Settlement Agreement and Release (New York)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1208				ABB_TEVA001522 - ABB_TEVA001536	12/7/2010	State Settlement Agreement and Release (North Carolina)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1209				ABB_TEVA001536 - ABB_TEVA001551	12/7/2010	State Settlement Agreement and Release (North Dakota)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1210				ABB_TEVA001552 - ABB_TEVA001567	12/7/2010	State Settlement Agreement and Release (Ohio)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1211				ABB_TEVA001568 - ABB_TEVA001584	12/7/2010	State Settlement Agreement and Release (Oklahoma)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)

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DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1212				ABB_TEVA001585 - ABB_TEVA001600	12/7/2010	State Settlement Agreement and Release (Oregon)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1213				ABB_TEVA001601 - ABB_TEVA001615	12/7/2010	State Settlement Agreement and Release (Pennsylvania)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1214				ABB_TEVA001616 - ABB_TEVA001630	12/7/2010	State Settlement Agreement and Release (Rhode Island)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1215				ABB_TEVA001631 - ABB_TEVA001645	12/7/2010	State Settlement Agreement and Release (South Carolina)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1216				ABB_TEVA001646 - ABB_TEVA001660	12/7/2010	State Settlement Agreement and Release (South Dakota)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1217				ABB_TEVA001661 - ABB_TEVA001675	12/7/2010	State Settlement Agreement and Release (Tennessee)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1218				ABB_TEVA001676 - ABB_TEVA001690	12/7/2010	State Settlement Agreement and Release (Texas)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1219				ABB_TEVA001691 - ABB_TEVA001705	12/7/2010	State Settlement Agreement and Release (Utah)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1220				ABB_TEVA001706 - ABB_TEVA001720	12/7/2010	State Settlement Agreement and Release (Vermont)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1221				ABB_TEVA001721 - ABB_TEVA001736	12/7/2010	State Settlement Agreement and Release (Virginia)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1222				ABB_TEVA001737 - ABB_TEVA001751	12/7/2010	State Settlement Agreement and Release (Washington)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1223				ABB_TEVA001752 - ABB_TEVA001766	12/7/2010	State Settlement Agreement and Release (West Virginia)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1224				ABB_TEVA001767 - ABB_TEVA001781	12/7/2010	State Settlement Agreement and Release (Wisconsin)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)
1225				ABB_TEVA001782 - ABB_TEVA001796	12/7/2010	State Settlement Agreement and Release (Wyoming)	802, 403, 402 (subject to the parties' 9/29/11 stipulation)

EXHIBIT N

DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)
1226			SIM-366 (Sacks)	ABB_SIM00566451 - ABB_SIM00566455	6/26/1989	Alderman, et al., *Effect of a Modified, Well-Tolerated Niacin Regimen on Serum Total Cholesterol, High Density Lipoprotein Cholesterol and the Cholesterol to High Density Lipoprotein Ration* , 64 Am. J. Cardiol., pp. 725-729 (1989)	403 (cumulative), Lack of foundation for date description
1227			SIM-368 (Sacks)	ABB_S2_00023217 - ABB_S2_00023395	4/29/1996	Kos Pharmaceuticals, Inc. NDA 20-381, Integrated Summary of Efficacy (Revision 1)	403 (cumulative), Lack of foundation for date description
1228			SIM-373 (Sacks)	ABB_SIM00550560 - ABB_SIM00550566	08/15/1994	Gray, et al., *Efficacy and Safety of Controlled-Release Niacin in Dyslipoproteinemic Veterans,* 121 Ann. Intern. Med., pp. 252-258 (1994)	403 (cumulative)
1229			SIM-374 (Sacks)	TV0145096 - TV0145110	04/26/2006	Knopp, et al., *The SLIM study: Slo-Niacin ® and Atorvastatin Treatment of Lipoproteins and Inflammatory Markers in Combined Hyperlipidemia,* 3 J. Clin. Lipid., pp. 167-178 (2009)	403 (cumulative), Lack of foundation for date description
1230			SIM-377 (Sacks)	ABB_S2_00000037 - ABB_S2_00000245	05/03/1996	Kos Pharmaceuticals, Inc. NDA 20-381, Niacin Sustained-Release Tablets	106
1231			SIM-378 (Sacks)	TV0005560 - TV005586	01/04/1995	File History for U.S. Patent Number 6,080,428 Excerpt: Continuation-In-Part Patent Application	403 (cumulative), Lack of foundation for date description
1232			SIM-379 (Sacks)	ABB_S2_00113611 - ABB_S2_00113775		Protocol No. 91/09, Interim Report: A Multi-Center, Open-Label Trial of the Long-Term Safety and Efficacy of Niaspan™ in Patients with Primary Hyperlipoproteinemia	106, 403 (cumulative)
1233						Curriculum Vitae, Phillip A. Beutel	
1234					01/01/1989	Pharmaceutical Dosage Forms: Tablets Vol. 1, 2 ed., Lieberman et al. eds, Marcel Denker Inc., 179-98 (1988)	106, Lack of foundation for date description
1235				WT0176219 - WT0176235	01/01/1988	Pharmaceutics: The Science of Dosage Form Design, Michael E. Aulton Ed. (1988)	403 (cumulative), Lack of foundation for date description
1236			SIM-352 (partial)	USLT000689	12/20/1994	Butler Pharmapac Formula Master product description for Slo-Niacin granulation (1st page of DTX 834)	802
1237			SIM-352 (partial)	USLT000708	12/6/1989	Memo from Tom G. to Ed. H and Vickie O. re sustained release niacin production dissolution results (selected page from DTX 834)	802

EXHIBIT N

DTX No.	PTX No.	JTX No.	Depo Exh No(s).	Production Range	Date	Description	Objection(s)

Defendants reserve the right to offer into evidence duplicate copies and/or original versions of any of the documents listed on the exhibit list.

Defendants reserve the right to use, or mark for identification, the reports and documents relied upon by Plaintiffs' experts as well as Plaintiffs' discovery responses, disclosures, contentions, and declarations filed by or on behalf of Plaintiff or its predecessors.

Defendants reserve the right to use and/or introduce at trial any trial exhibit identified by Plaintiffs on their exhibit list.

By listing documents on the attached exhibit list, Defendants do not concede the relevance, foundation, and/or admissibility of any of those documents. Further, Defendants have listed certain documents produced by Plaintiffs for purposes of rebutting arguments that Plaintiffs may raise. By listing those rebuttal documents, Defendants do not concede the admissibility or relevance of these exhibits at trial.

EXHIBIT O

FILED SEPARATELY UNDER SEAL

EXHIBIT P

EXHIBIT P – WATSON'S STATEMENT OF ADDITIONAL MATTERS

Watson objects to Abbott's Statement of Additional Matters points 2 through 5 because those matters were first added on December 21 and 29, 2011, which is well after the parties' agreed upon November 21, 2011 pretrial order exchange. Watson also disputes the merits of Abbott's Additional Matters.

Moreover, Abbott has not yet disclosed which fact witnesses it will call live at trial. Because of this, Watson has not yet designated the deposition testimony of witnesses that Abbott indicated that it may call live. The Court should require Abbott identify those witnesses it will call live witnesses within one week so that Watson can prepare for cross-examination of Abbott's live trial witnesses or designate the deposition testimony of those it will not be calling live at trial.